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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

City of Providence, individually and on behalf of all others similarly situated, Plaintiff, v. Celgene Corporation, Defendant.	Civil Action No._____ CLASS ACTION COMPLAINT **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT

Plaintiff City of Providence ("Plaintiff" or "Providence") residing at 25 Dorrance Street, Providence, Rhode Island 02903 brings this class action on behalf of itself and all other similarly situated third-party payors and consumers against Celgene Corporation ("Celgene"). Based on personal knowledge as to facts

pertaining to it, and upon information and belief as to all other matters, Plaintiff alleges as follows:

I. NATURE OF THE ACTION

1. This is a civil antitrust action seeking damages arising out of Celgene's unlawful exclusion of competition from, illegal monopolization of, and restraint of trade in the market for thalidomide (sold by Celgene under the brand-name Thalomid®) and lenalidomide (sold by Celgene under the brand-name Revlimid®).

2. Thalidomide was originally developed in Germany in the 1950s and, until 1962, was marketed in Europe as a highly effective sleeping pill and as a treatment for nausea, or morning sickness, in pregnant women. However, in 1962, thalidomide was banned worldwide after researchers discovered that it caused severe birth defects.

3. Although the FDA refused to approve thalidomide in the 1960s, it approved Celgene's application for the drug in 1998 as a treatment for erythema nodosum leprosum – a form of leprosy. Today, in combination with dexamethasone (a steroid), Thalomid is also indicated for the treatment of multiple myeloma. Revlimid, an analogue of Thalomid, is also used to treat multiple myeloma.

4. Both Thalomid and Revlimid are sold in capsule form and are administered orally. While Thalomid and Revlimid are effective treatments for leprosy and multiple myeloma, they are also known human teratogens, *i.e.* they can cause significant or life-threatening birth defects when ingested by pregnant women. Accordingly, following public awareness of these defects, the FDA conditioned approval of these drugs on Celgene's implementation of restricted distribution programs. The first was S.T.E.P.S, implemented in 1998, and subsequently changed to the Risk Evaluation and Mitigation Strategies ("REMS") in 2010.[1] The REMS programs for Thalomid and Revlimid are known as Thalomid REMS® and Revlimid REMS® (formerly known as the RevAssist® program), respectively. Pursuant to the REMS programs, distributors, pharmacists and patients are required to enroll in the REMS programs before obtaining Thalomid or Revlimid.

5. Celgene's revenues from sales of Thalomid and Revlimid have dramatically increased in the last six years, as a direct result of Celgene's unlawful assertion of its monopoly over the markets for these drugs. From 2009 to 2013, Celgene generated approximately $17.1 billion in revenue from the sales of Thalomid and Revlimid. Through the first three quarters of 2014, Celgene

[1] *See* http://www.ncbi.nlm.nih.gov/pubmed/10211535; *see also* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM222649.pdf.

generated approximately $3.66 billion in revenue from sales of Revlimid and approximately $164 million from sales of Thalomid.[2] Celgene charges between $212 and $357 per capsule for Thalomid, or between 3400% and 5850% more per capsule than when Thalomid was first approved by the FDA. Celgene charges approximately $500 per capsule of Revlimid.

6. No AB-rated generic version of Thalomid or Revlimid has come to market due to Celgene's unlawful interference with generic manufacturers' attempts to develop generic equivalents. Celgene has unlawfully perpetuated its monopoly over the markets for Thalomid and Revlimid by: (1) using the Thalomid and Revlimid REMS programs that were designed to ensure safe access to Thalomid and Revlimid as a pretext to delay and indefinitely postpone the availability of significantly less expensive generic alternatives to these drugs; (2) fraudulently obtaining use patents on the procedures that ensure safe use of Thalomid and Revlimid in order to block generic entrants, *i.e.* Celgene's potential competitors, from coming to market; (3) engaging in sham litigation against any potential competitor who was able to obtain samples of Thalomid and Revlimid for use in generic bioequivalence testing; and (4) abusing the Citizen Petition process.

7. Celgene has taken deliberate and intentional measures to block potential competitors from bringing generic thalidomide and lenalidomide to

[2] Celgene Corporation and Subsidiaries, Sales Breakdown – U.S. vs. International.

market resulting in significant harm to Plaintiff and the class of end-payors it seeks to represent. Due to Celgene's monopolistic and anticompetitive conduct, Plaintiff, and all other consumers and third-party payors, paid higher prices to treat leprosy and multiple myeloma than they otherwise would have absent Celgene's conduct.

8. Plaintiff brings this action as a class action on behalf of all consumers and third party payors (collectively, "End Payors") who indirectly purchased, paid and/or provided reimbursement for Thalomid and/or Revlimid, other than for re-sale since November 7, 2010.

9. Plaintiff asserts claims for compensatory and/or treble damages for violations of the State laws enumerated below.

II. JURISDICTION AND VENUE

10. Plaintiff brings this action under Section 16 of the Clayton Act, 15 U.S.C. § 26, to obtain equitable and injunctive relief for violations of Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2. The court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337 for claims that arise under federal and state law, respectively. Plaintiff also asserts claims for damages, restitution, and other relief, under state antitrust, unfair competition, consumer protection and unjust enrichment laws.

11. The Court additionally has subject matter jurisdiction over these state law claims under 28 U.S.C. § 1367 because those claims are so related to the federal claim that they form part of the same case or controversy.

12. The Court further has subject matter jurisdiction over the state law claims by virtue of the Class Action Fairness Act of 2005 ("CAFA"), which amended 28 U.S.C. §1332 to add a new subsection (d) conferring federal jurisdiction over class actions where, "any member of a class of Plaintiffs is a citizen of a State different from any Defendant" and the aggregated amount in controversy exceeds $5,000,000, exclusive of interest and costs. The $5,000,000 amount-in-controversy and diversity-of-citizenship requirements of CAFA are satisfied here.

13. Venue is appropriate within this District under Section 12 of the Clayton Act, 15 U.S.C. §22 and 28 U.S.C. §1391(b) and (c), because Defendant transacts business within this District, and/or has an agent and/or can be found in this District, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this District.

III. THE PARTIES

14. Plaintiff City of Providence is a municipal corporation with a principal address of 25 Dorrance Street, Providence, Rhode Island. Providence is a self-insured health and welfare benefit plan, and provides reimbursement for some

or all of the purchase price of prescription drugs, including Thalomid and Revlimid. Providence provided reimbursement for some or all of the purchase price of Thalomid and Revlimid for its active and retired public employees and their dependents who reside in and/or purchased Thalomid and Revlimid in Florida, Kansas, Massachusetts, New Jersey, North Carolina, and Pennsylvania.

15. Defendant Celgene is a corporation organized and existing under the laws of Delaware, having its principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

16. All of Defendant's wrongful actions described in this complaint are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or undertaken by Defendant's various officers, agents, employees, or other representatives while actively engaged in the management of Defendant's affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendant.

IV. BACKGROUND REGARDING THE PHARMACEUTICAL INDUSTRY

A. Monopoly Power of Brand-Name Manufacturers in the Pharmaceutical Market

17. Most product markets are characterized by a traditional consumer-seller framework, wherein the consumer chooses the good to be purchased and tenders payment for that good. In this traditional framework, the consumer is the decision-maker and often decides what product to purchase based, in large part, on price. Thus, the seller has an incentive to set a competitive price that will entice consumers while maintaining profitability. However, the pharmaceutical market is markedly different from this traditional framework, allowing the seller (here, the drug manufacturer) to exploit its monopoly power.

18. In the American pharmaceutical market, many drugs, including Thalomid and Revlimid, are only available with a physician's prescription. Thus, in the pharmaceutical market, it is the physician – not the consumer – that chooses which drug the consumer will purchase.

19. Because physicians often control the decision of which drug the consumer will purchase, brand-name drug manufacturers often employ sales forces to promote their products to physicians. However, these sales representatives do not make the physician aware of the relative costs of the drugs they promote. In fact, studies show that physicians are generally unaware of the costs of the drugs

they prescribe and, because they do not purchase the drugs themselves, are insensitive to price. Thus, the selection of drugs is not significantly influenced by cost. Moreover, where multiple manufacturers sell drugs that treat similar medical conditions, those products are often sold at relatively similar, high prices. Thus, unlike in a traditional market, consumers do not benefit from competition between similar brand-name drugs.

20. Celgene is able to charge supracompetitive prices for Thalomid and Revlimid because it possesses monopoly power – *i.e.*, the ability to raise prices above competitive levels without losing sales. First, as discussed above, even where more than one brand-name drug is available to treat a condition, the choice between these drugs is not dictated by price, but rather by the prescribing physician. Second, the price elasticity of demand – the extent to which sales go down when price goes up – is also low. As a result of Celgene's monopoly, there are no other alternatives; thus, Celgene maintains a supracompetitive price without losing sales.

21. Recognizing the increasing cost of healthcare and lack of competitive forces in the prescription drug market, Congress enacted the Hatch-Waxman Act, discussed in further detail below, authorizing the manufacture and sale of generic drugs. Unlike brand-name drug manufacturers, generic drug manufacturers do not employ large sales forces and generally set their prices for their AB-rated drugs

much lower than the corresponding brand-name drug. Thus, when generic drugs enter the market, consumers can benefit from price competition. Since the enactment of Hatch-Waxman, every state has introduced drug substitution laws that permit or require pharmacists to substitute an available AB-rated generic drug where the corresponding brand-name drug has been prescribed (unless the prescribing physician specifically orders otherwise by writing "dispense as written" or similar language on the prescription), thus giving consumers the opportunity to benefit from price competition and reducing the brand-name manufacturers' monopoly power.

22. By preventing generic manufacturers from successfully entering the market with generic versions of Thalomid and Revlimid, Defendant illegally maintained its monopoly to the detriment of end-payors like Plaintiff and members of the Class who otherwise would have directly benefitted from increased competition brought by generic entry.

B. The Relationship Between Brand-Name and Generic Drugs

23. Before it is able to sell a new drug, a brand-name drug manufacturer must obtain FDA approval for that drug. Thus, pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), the brand-name manufacturer must submit a New Drug Application ("NDA"). 21 U.S.C. §§ 301 *et seq*. The NDA must include information about the drug, including with regard to the drug's safety and

effectiveness, and information regarding any applicable patents. 21 U.S.C. § 355(a), (b).

24. If the FDA approves the NDA, the drug is listed in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations,* which is commonly referred to as the Orange Book. The manufacturer can list any patents in the Orange Book that it believes could reasonably be asserted against a generic manufacturer that makes, uses or sells a generic version of the brand-name drug before the expiration of the listed patents. 21 U.S.C. §355(b)(1). Moreover, if the brand-name drug manufacturer obtains a new patent after obtaining FDA approval for the drug, it may list such patent in the Orange Book within thirty days of the patent's issuance. 21 U.S.C. §355(c)(2).

25. The FDA does not have the necessary resources to validate all patents listed in the Orange Book by brand-name drug manufacturers. Thus, the FDA relies on the brand-name drug manufacturer to provide truthful and accurate information about the manufacturer's patents and their applicability to the drug at issue.

26. In order to stem the tide of rising healthcare costs by encouraging generic entrants into expensive drug markets, Congress enacted the Hatch-Waxman Act in 1984. Hatch-Waxman simplified the process for obtaining FDA approval of a generic equivalent of a brand-name drug. Specifically, instead of

requiring a generic manufacturer to file a costly NDA, it may instead file an abbreviated new drug application ("ANDA"). While an ANDA relies on the scientific findings of safety and effectiveness set forth in the NDA, it must show that the proposed generic equivalent (i) contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and (ii) is absorbed at the same rate and to the same extent as the brand drug. 21 U.S.C. § 355(j)(8)(B). In other words, the ANDA must show that the generic drug is therapeutically equivalent – *i.e.* both pharmaceutically equivalent and bioequivalent – to the brand drug. If the FDA finds that a generic is therapeutically equivalent to its brand-name counterpart, the FDA assigns an "AB" rating to the generic drug.

27. Generics contain the same active ingredient as the brand-name counterpart – also called the reference listed drug ("RLD") – and, because they are therapeutically equivalent to the RLD, are as safe and effective. Thus, a generic drug may be substituted for the RLD because it contains identical amounts of the same active ingredients, is administered in the same form and dosage, and meets applicable standards of strength, quality, purity and identity.

28. The only material difference between a generic drug and the RLD is the price. A recent Federal Trade Commission ("FTC") report notes that "the first generic competitor enters the market at a price that averages approximately 80

percent of the brand-name counterpart, and gains substantial share from the brand-name product in a short period of time." As the number of generic market participants increases, the price of the generic drug falls even further. Thus, the FTC reports that subsequent generic entrants can enter the market with a generic drug priced at "80 percent or more off the price of the brand-name drug." The FTC estimates that about one year after market entry, a generic drug takes over 90% of the brand-name drug's unit sales at a deeply discounted price. *See, e.g.*, *Generic Pharmaceuticals, Note by the United States*, Organisation for Economic Co-operation and Development Competition Committee (June 18-19, 2014).

29. Moreover, as discussed above, state substitution laws allow or require pharmacists to substitute the less expensive generic for the more-expensive brand-name drug. These substitutions are incentivized by federal reimbursement rules and the industry pricing structure, allowing pharmacies to earn a higher markup on generic drugs than on brand-name drugs. Private health insurers provide similar incentives to pharmacies to substitute cheaper generic drugs for more expensive brand-name drugs. These health insurers, who are obligated to cover much of the cost of their insureds' prescription drugs, also incentivize their insured to choose the generic drug by offering lower copays.

30. Thus, by creating the accelerated ANDA process that allows generic drugs to enter the market, Hatch-Waxman reduces healthcare costs. In addition to

its goal of reducing healthcare costs, Congress also enacted Hatch-Waxman to incentivize innovation and development of new drugs by brand-name manufacturers. Since the enactment of the Hatch-Waxman Act, the rate at which generic drugs have penetrated the drug market has steadily increased, while brand-name manufacturers continue to innovate and develop new drugs.

31. Increased generic drug competition benefits all consumers by enabling them to (i) purchase a generic version of a drug at a substantially lower price; and/or (ii) purchase a brand-name drug at a reduced price. However, unless and until the generic drug makes it to market, competition is stifled by the monopoly power of the brand-name drug, allowing the brand-name drug manufacturer to reap enormous revenues while charging supracompetitive prices. As a result, brand-name drug manufacturers like Defendant Celgene have a strong incentive to delay the arrival of generic drug competition. As discussed below, Celgene does so through, *inter alia*, blocking generic manufacturers' access to drug samples needed to perform bioequivalence testing, improper patent listing, sham patent litigation and abuse of the Citizen Petition process.

C. The Regulatory Structure under Hatch-Waxman

i. Listing Patents in the Orange Book

32. The Hatch-Waxman Act delineates a process for identifying and addressing patents that may apply to brand-name and generic drug products. The

FDA includes such patent information relevant to each NDA in the Orange Book. A generic manufacturer seeking to file an ANDA must submit patent certifications or statements, described more fully below, as to each patent listed in the Orange Book for the relevant NDA.

33. Specifically, the brand-name manufacturer is required to provide the FDA with information about "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(G).

34. When Celgene originally submitted patent information regarding the Thalomid and Revlimid patents, the relevant statute required the NDA applicant to list "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C.A. § 355(b)(1) (effective 1999 & 2002).

35. The then-applicable regulations identified three types of patents that could properly be listed: "drug substance (ingredient) patents, drug product (formulation and composition) patents, and method of use patents." 21 C.F.R. §

314.53(b) (effective 1999 & 2002). The regulations further provided that "[f]or patents that claim a drug substance or drug product, the [NDA] applicant shall submit information only on those patents that *claim a drug product that is the subject of a pending or approved application*, or that claim a drug substance that is a component of such a product." *Id.* (emphasis added). The NDA holder also could properly list a patent for a drug product only "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale *of the drug product*." *Id.* (emphasis added). Thus, an NDA applicant could submit information describing the patent as a "drug product patent" only if the patent claimed the specific drug product that was the subject of the NDA.

36. NDA applicants are required, pursuant to the regulatory framework, to make declarations supporting the patents it lists in the Orange Book, and to properly identify whether the patent is a "drug, drug product, or method of use" patent. 21 C.F.R. § 314.53(c)(2)(ii) (effective 1999 & 2002). However, the FDA has admitted that it does not have the "resources" or "expertise" to review the patent information submitted by NDA applicants. *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50343-45 (Oct. 3, 1994). Thus, the process of listing patents in the Orange Book is largely done on the "honor system."

ii. Paragraph IV Certifications and Section viii Statements

37. Where the NDA holder has submitted patent information describing a listed patent as claiming a relevant drug substance or drug product, an ANDA applicant must certify that the generic drug will not infringe those patents. Pursuant to Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications: (1) that no patent information for the brand-name drug has been filed with the FDA; (2) that the patent for the brand-name drug has expired; (3) that the patent for the brand-name drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date; or (4) that the patent for the brand-name drug is invalid or will not be infringed by the generic drug manufacturer's proposed product. The final category of certification is referred to as a "Paragraph IV Certification."

38. The distinction between patents described as containing relevant drug product claims and patents described as containing only method-of-use claims is important. If the brand-name manufacturer describes the patent as containing a relevant drug product claim, the ANDA applicant must file a Paragraph IV Certification, certifying that the patent is invalid, unenforceable, or would not be infringed by the generic product if it wishes to bring its generic drug to market before the relevant patent expires. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

39. If the generic drug manufacturer files a Paragraph IV Certification, the brand-name manufacturer can obtain an automatic 30-month stay on the generic's market entry by filing a patent infringement lawsuit against the ANDA applicant ("Paragraph IV Litigation"). Importantly, Paragraph IV litigation has the effect of delaying all generic competition because the FDA is prohibited from approving any other generic manufacturer's ANDA until 180 days after the first-filer to submit a Paragraph IV Certification has entered the market. 21 U.S.C. § 355(j)(5)(B)(iv).

40. However, if, rather than describing the patent as containing a relevant drug product claim, the brand-name manufacturer describes the patent as containing method-of-use claims, the ANDA applicant may be able to submit what is known as a "Section viii Statement." 21 U.S.C. § 355(j)(2)(A)(viii); 21 C.F.R. §314.94(a)(12)(iii). Section viii Statements state that the ANDA applicant is not seeking approval for the particular use covered by the method-of-use patent. Most significantly, where the ANDA applicant makes only a Section viii Statement, the brand-name manufacturer cannot obtain an automatic 30-month stay on generic market entry even if it sues the ANDA applicant for patent infringement. Moreover, because the 180-day exclusivity period only applies where the ANDA applicant submits a Paragraph IV Certification, the FDA can approve an ANDA

containing only a Section viii Statement *without regard* to whether any other ANDA applicant is otherwise entitled to a 180-day exclusivity period.

41. Per FDA regulations, ANDA applicants submit Paragraph IV Certifications and Section viii Statements based on the patent information (*i.e.*, whether the patent claims a drug product or a method of use) submitted by the brand-name manufacturer to the FDA and listed in the Orange Book – not on the claims in the actual patent. Thus, there are two important advantages to be gained by a brand-name manufacturer in describing a patent as containing a relevant drug product claim. First, it can easily obtain an automatic 30-month stay on generic competition by filing a patent infringement claim. Second, because the first generic filer to enter the market receives 180 days of market exclusivity, the brand-name manufacturer can delay all generic competition by paying the first generic filer to delay entry into the market.

D. Overview of Common Tactics Employed By Patent Holders To Delay Entry Of Competitive Generics

i. Paragraph IV Litigation

42. Under the regulatory scheme, the FDA delays approval to generics, but only if certain requirements are met. Specifically, if an ANDA applicant submits a Paragraph IV Certification and the brand-name drug manufacturer initiates Paragraph IV Litigation within forty-five days of receiving notification of the Paragraph IV certification, the FDA will not grant final approval to the ANDA

until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic drug manufacturer's ANDA. Moreover, if the ANDA application is otherwise in order and would otherwise be approved but for the 30-month stay, the FDA can grant "tentative approval." However, until one of the above-stated events occurs, the FDA cannot authorize final approval for the generic drug manufacturer to market its product.

43. As noted above, Hatch-Waxman sought to decrease healthcare costs through the introduction of generic drug competition. Accordingly, it incentivizes generic manufacturers to be the first to file an ANDA containing a Paragraph IV Certification by granting that manufacturer a period of protection from competition from other generic versions of the drug. For Paragraph IV Certifications made before December 8, 2003, the first ANDA applicant received 180 days of market exclusivity, which could not be forfeited and was triggered only by commercial marketing of the generic product. For Paragraph IV Certifications made after December 8, 2003, the first ANDA applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs).

44. This framework can be easily manipulated. As described above, where the brand-name manufacturer has described its patents as containing relevant drug product claims – even where the patents do not actually contain such

claims – brand-name manufactures can use Paragraph IV Litigation to delay generic entry and prolong their monopoly power. Due to the automatic 30-month stay on generic competition granted where the brand-name manufacturer commences Paragraph IV Litigation within 45 days of notification, it is advantageous for the brand-name manufacturer to file such litigation even where the generic does not actually infringe its patents and the lawsuit has no merit. In fact, the use of meritless litigation is pervasive. According to a 2002 FTC study entitled "Generic Drug Entry Prior to Patent Expiration: An FTC Study," generic manufacturers "prevailed in 73% of the cases in which a court has resolved the patent dispute."

45. Before the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") enacted on December 8, 2003, the first ANDA applicant to submit a Paragraph IV Certification could help a brand-name manufacturer delay all generic competition by agreeing not to begin marketing its generic drug for a certain period of time. This tactic, called exclusivity "parking," created a bottleneck because later ANDA applicants could not enter the market until the first approved generic drug manufacturer had enjoyed its 180-day exclusivity period.

46. To prevent this abusive delay tactic, Congress enacted the MMA in December 2003. The MMA outlined a number of conditions under which an

ANDA applicant forfeits its eligibility for 180-day exclusivity, allowing other ANDA applicants to launch their generic drug products during the 180-day period. For example, forfeiture occurs if the first ANDA applicant fails to obtain tentative approval within 30 months from filing, unless the failure is caused by a change in, or review of, the approval requirements.

47. Under the "failure to market" provision, the first-to-file ANDA applicant forfeits 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents qualifying the first applicant for exclusivity (*i.e.*, as to each patent for which the first applicant submitted a Paragraph IV Certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment including a finding the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the FDA Orange Book.

48. Brand-name drug manufacturers and first-filing generic drug manufacturers have skirted the forfeiture provisions and kept the 180-day exclusivity period intact by, for example, settling their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV Certification, or

seeking a consent judgment that does not include a finding that all of the patents for which the fist applicant submitted a Paragraph IV Certification were invalid or not infringed. Such settlements prevent other ANDA applicants from entering the market unless they are able to trigger the forfeiture conditions by obtaining a judgment that all patents listed in the first-generic-filer's Paragraph IV Certifications are invalid or not infringed. In order to obtain such a judgment, subsequent ANDA applicants may need to initiate a declaratory judgment action concerning patents that the brand-name drug manufacturer did not assert against the first-generic-filer in a Paragraph IV Litigation. Thus, strategic but sham settlements between brand-name and first-to-file generic manufacturers can severely delay generic competition.

ii. Use of Citizen Petitions to Delay the FDA Approval of Generic Drugs

49. In addition to Paragraph IV Litigation, brand-name manufacturers can use FDA Citizen Petitions to delay generic competition.

50. Pursuant to Section 505(j) of the Food, Drug and Cosmetic Act, a person may file a petition, referred to as a "Citizen Petition," with the FDA to formally state his or her concerns regarding a drug product. The subject matter of a Citizen Petition is not restricted and petitions can be filed before or after a drug enters the market.

51. The FDA must respond to each Citizen Petition within 180 days of receipt. In its response, the FDA Commissioner can approve the request in whole or in part, or deny the request. Furthermore, the Commissioner may provide a tentative response with an estimate on a time for a full response.

52. The process of reviewing and responding to Citizen Petitions is extraordinarily time consuming, especially given the FDA's limited resources, because, even if the petition is meritless, the FDA is required to respond to it. Responses require research of the petition's subject and examination of scientific, medical, legal and sometimes economic issues. Responses may also require multiple reviews within the FDA and a coordinated response effort. The FDA has stated that "[i]t is very rare that petitions present new issues that [the Center for Drug Evaluation and Research "CDER"] has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the citizen petitions." Thus, brand-name manufacturers are aware that filing bogus Citizen Petitions can directly impact and delay FDA approval of generic drugs.

53. Brand-name manufacturers can charge supracompetitive prices for as long as they are able to stave off generic competition. Thus, not surprisingly, brand-name manufacturers use Citizen Petitions, sometimes submitted long after an ANDA application is filed, to delay generic entry. This delay can translate into millions of dollars in additional profit for the brand-name manufacturers even if

the Citizen Petition only causes a short delay before the arrival of generic competition.

54. In fact, in a 2012 report of the Commissioner of Food and Drugs, the FDA expressly acknowledged that the agency is concerned that brand-name manufacturers may file Citizen Petitions "that do not raise valid scientific issues and are intended primarily to delay the approval of competing drug products." The FDA went on to say that "innovator companies may be implementing strategies to file serial 505(q) petitions and petitions for reconsideration in an effort to delay approval of ANDAs [] for competing drugs."

iii. Authorized Generics

55. Brand-name drug manufacturers are entitled to market a generic version of their own brand-name drug even if a generic manufacturer would be entitled to 180 days of exclusivity under the first-to-file construct. Authorized generics are chemically identical to their brand-name counterparts, but are sold as generics through either the brand-name manufacturer's generic subsidiary (if it has one) or through a third-party generic drug manufacturer.

56. Authorized generics can have a profound effect on generic drug competition. For example, in its recent study, Authorized Generic Drugs: Short-term Effects and Long-Term Impact (August 2011) (the "FTC Study"), the FTC found that authorized generics capture a significant market share, thereby driving

the price of the generic drug down and drastically reducing the generic manufacturer's profits during the 180-day exclusivity period. Specifically, the FTC study found that, during the 180-day exclusivity period, the presence of an authorized generic reduced the first-filer generic's revenues by 40 to 52 percent. Thus, consumers can benefit from the market presence of an authorized generic as overall prices are driven down during the generic manufacturer's 180-day exclusivity period.

57. However, because the market presence of an authorized generic significantly impacts the revenue brought in by the generic manufacturer, a brand-name manufacturer's agreement not to launch an authorized generic drug is extremely valuable to the generic drug manufacturer.

58. Thus, brand-name drug manufacturers have found ways to compensate generic manufacturers for delaying marketing of their generic products, cloaking them in the guise of seemingly legitimate agreements. While these agreements are mutually beneficial to brand-name and generic drug manufacturers, they stifle competition and deprive consumers and other drug purchasers, such as Plaintiff and members of the putative class, of the lower prices resulting from competition between the brand-name and generic drug, and competition between multiple generic drugs.

V. CELGENE'S ANTICOMPETITIVE CONDUCT

59. As discussed in paragraphs 2-4, Thalomid and Revlimid have dangerous side effects for pregnant women, as they are known human teratogens that cause serious fetal abnormalities. Thus, in order to ensure patient safety, these drugs are only distributed through Celgene's REMS programs.

60. Generic manufacturers need sample quantities of Thalomid and Revlimid in order to perform bioequivalence studies before submitting ANDAs. However, due to Celgene's REMS program, generic manufacturers are unable to purchase Thalomid and Revlimid samples through normal wholesale distribution channels. Instead, the drugs are only available through Celgene. Celgene has refused to provide any such samples to generic drug manufacturers for bioequivalence testing (although, as described below, it has provided samples to other entities for *inter alia* research purposes), stating that to do so would violate its REMS programs.

A. Celgene Monopolized the Relevant Markets by Refusing to Sell Samples of Thalomid and Revlimid to Generic Manufacturers

61. Celgene has developed an extensive anticompetitive scheme pursuant to which it has repeatedly refused to sell samples of Thalomid or Revlimid to any generic manufacturer for bioequivalence studies, claiming that to do so would violate its REMS programs. This anticompetitive scheme has prevented generic

competition, thus prolonging Celgene's monopoly and causing significant financial harm to consumers.

62. Congress intended that REMS programs would raise awareness of and safeguard the public from improper use of pharmaceuticals. However, Celgene has illegally used its Thalomid and Revlimid REMS programs to delay and indefinitely postpone the availability of generic alternatives to Thalomid and Revlimid by refusing to sell samples of Thalomid or Revlimid to numerous generic manufacturers, including Mylan Pharmaceuticals ("Mylan") between 2004 and the present, Lannett Company ("Lannett") in 2006, and Dr. Reddy's Laboratories ("Dr. Reddy's") in 2008 and 2009. In all cases, it has used its REMS programs as a pretextual justification for its refusal. Such refusal directly contravenes the 2007 Food and Drug Administration Amendments Act ("FDAAA"), which explicitly states that REMS provisions may not be used for such purposes. Specifically, FDAAA subsection f(8) provides: "No holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application under section 505(b)(2) or (j) or to prevent application of such element under subsection (i)(1)(B) to a drug that is the subject of an abbreviated new drug application." 21 U.S.C. § 355-1(f)(8).

63. The FDA has advised that REMS should not be used as a pretext to

block or delay generic competition. Most recently, in December 2014, the FDA issued draft guidance stating that the "FDA will not consider it a violation of the REMS for the RLD sponsor to provide a sufficient quantity of the RLD to the interested generic firm or its agent to allow the firm to perform the testing necessary to support its ANDA." *See* How to Obtain a Letter From FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD, FDA (December 2014), at 1.

64. Moreover, the FDA has explicitly stated in letters to Celgene that Celgene may sell drugs, such as Thalomid and Revlimid, that are subject to restricted distribution programs to particular generic firms, including Lannett and Mylan, for bioequivalence testing without violating the corresponding REMS programs.

65. It is clear that Celgene's refusal to provide samples to generic competitors based on concerns for violating its REMS programs is a mere anticompetitive pretext because, on numerous occasions, Celgene has granted access to Thalomid and Revlimid to non-competitor research organizations for the purpose of conducting clinical studies using these drugs. Like the generic manufacturers who have sought samples of Thalomid and Revlimid, such research organizations have not been enrolled in the relevant REMS programs.

66. Specifically, Celgene provided Thalomid to the Johns Hopkins

University School of Medicine in order to conduct clinical trials and provided Revlimid to international researchers at Intergroupe Francophone du Myelome, University Hospital of Toulouse, and Groupe Francophone Des Myelodysplasies, as well as the National Cancer Institute, Eastern Cooperative Oncology Group, Mayo Clinic, and MD Anderson Cancer Center in Houston, TX.

67. Moreover, in addition to its refusal to sell samples to generic manufacturers, Celgene has engaged in anticompetitive practices with other suppliers in order to retain its market monopoly.

i. Celgene Entered into an Exclusive Supply Contract with Seratec to Prevent Barr from Accessing Samples of Thalomid

68. Barr Laboratories ("Barr"), now a division of Teva Pharmaceuticals, was a global specialty pharmaceutical company known for developing, manufacturing, and marketing lower-priced generic versions of brand-name drugs. Barr sought to develop and market an AB-rated Thalomid equivalent.

69. In order to develop the generic version of a brand-name drug, the generic manufacturer must gain access to a sample supply of the original brand-name drug which contains the active pharmaceutical ingredient ("API"). The API is a necessary component of bioequivalence studies and validation testing required to be performed before the generics manufacturer can submit its ANDA to the FDA. In the ANDA, the applicant is required to identify the supplier of the API and the API supplier must submit a Drug Master File ("DMF") to the FDA,

which it considers along with the ANDA in determining whether to approve the ANDA.

70. Due to the REMS program, very few companies are capable of supplying the thalidomide API. In or about 2004, Barr contacted a French supplier of thalidomide API, Seratec S.A.R.L. ("Seratec") and obtained samples of the API for use in its required testing and corresponding ANDA application.

71. By September 2005, Barr had developed its proposed generic product and had completed its ANDA. However, in order to file its ANDA, Barr needed to procure a DMF from Seratec, because Seratec supplied Barr with the API. Before Barr could procure the DMF from Seratec, Celgene and Seratec entered into an exclusive thalidomide supply arrangement. Thus, Barr was never able to procure the required DMF. On information and belief, Celgene did not enter into the exclusive supply arrangement with Seratec for legitimate business purposes. Rather, Celgene required exclusivity from Seratec in order to interfere with potential generic competitors' ability to obtain the necessary API samples and to market a generic version of Thalomid.

72. Because Celgene's contract with Seratec prevented Barr from obtaining the necessary DMF, Barr was forced to find a different API supplier and, at great expense, to repeat its bioequivalence studies and validation testing. Subsequently, Barr was able to obtain the necessary API samples from a different

supplier. After re-doing its bioequivalence studies and validation testing, it submitted its ANDA for thalidomide on September 22, 2006. The ANDA showed that Barr's generic thalidomide product was bioequivalent to Celgene's brand-name Thalomid. The FDA accepted Barr's ANDA application for filing on December 4, 2006. Thus, but for the Celgene-Seratec agreement, which was designed to prevent Barr and other generic manufacturers from obtaining thalidomide API samples, a lower-priced generic thalidomide would have come to market much earlier. As discussed below, Celgene further interfered with Barr's ANDA and Barr's generic thalidomide product never came to market.

ii. Celgene Refused to Sell Samples of Thalomid to Lannett Despite the FDA's Express Approval to Do So

73. Like Barr, Lannett is a generic pharmaceuticals manufacturer that sought to develop and market a generic version of Thalomid. Like Barr, Lannett sought to obtain samples of thalidomide API to perform the necessary bioequivalence studies and validation testing. Thus, Lannett wrote to the FDA in a letter dated September 6, 2006, requesting FDA approval to obtain Thalomid samples for use in bioequivalence testing.

74. In February 2007, the FDA Office of Generic Drugs ("OGD") responded to Lannett's request, stating that "it is not agency's [sic] intention to permit the restrictions of the [Thalomid REMS] program to prevent manufacturers of generic drugs from obtaining Thalomid for use in the bioequivalence testing

necessary to obtain approval of an abbreviated new drug application for a thalidomide product."

75. The OGD letter went on to explain:

> To ensure that the intention of Congress in enacting the Generic Drug Approval Provisions in Section 505(i) is not frustrated by the terms of the [Thalomid REMS] program, FDA has notified Celgene that the agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid. . . for the purpose of conducting bioequivalence testing.

76. On July 26, 2007, Arthur P. Bedrosian, President and CEO of Lannett, wrote to Celgene:

> In order to complete our bio-study, the FDA has instructed us to purchase 250 Thalomid 200 MG Capsules from you. We kindly request information as to how to best carry out this transaction. We will be happy to supply a purchase order once you provide us with the total product cost. Submitted with this document, you will find the appropriate licenses necessary for us to purchase product from you. We kindly ask that you inform us of any additional information you will need to complete this transaction.

77. On or about September 27, 2007, Lannett faxed to Celgene, at Celgene's request, a copy of the FDA letter sent to Lannett, which authorized Lannett to acquire Thalomid samples from Celgene. However, despite receiving Lannett's letter and purchase order and the FDA authorization letter, Celgene refused to fill Lannett's purchase order.

78. On January 14, 2008, Lannett filed a complaint against Celgene seeking, *inter alia*, mandatory injunctive relief requiring Celgene to provide Lannett with samples of Thalomid in order for Lannett to conduct its

bioequivalence study and verification testing as contemplated by the FDA's letter dated February 12, 2007.

79. Celgene and Lannett reached a confidential settlement in 2011.

iii. Celgene Refused to Sell Samples of Thalomid and Revlimid to Mylan Despite the FDA's Express Approval to Do So

80. Like Barr and Lannett, Mylan is a generic pharmaceuticals manufacturer. Mylan is based in Cecil Township, Pennsylvania, and is the second largest generic and specialty pharmaceuticals company in the world.

81. As it did with Barr and Lannett, Celgene refused to provide samples of Thalomid to Mylan. In fact, Mylan began attempting to obtain samples of Thalomid as early as October 2004. Mylan's attempts to obtain those samples are still ongoing more than ten years later.

82. Mylan began its development of a generic thalidomide product in September 2003. Like other manufacturers, Mylan attempted to obtain samples of Thalomid directly from Celgene beginning in October 2004. On October 5, 2004, Mylan sent a letter to Celgene through a third party requesting to purchase Thalomid capsules for the purpose of conducting bioequivalence studies. Celgene did not respond.

83. On May 3, 2005, Mylan repeated its request.

84. On June 21, 2005, Celgene finally responded. Celgene confirmed that Mylan would not be able to purchase Thalomid samples through normal wholesale

distribution channels. Celgene further explained that its Thalomid REMS (then S.T.E.P.S.) program required that all distribution of Thalomid be tracked, and stated that it was against Celgene's policy to deal with third parties in the sale of Thalomid samples.

85. Attempting to comply with Celgene's stated policy, on September 2, 2005, Mylan directly contacted Celgene, requesting to purchase Thalomid capsules for the purpose of developing a generic thalidomide product and to perform bioequivalence studies related thereto. Mylan told Celgene that the "FDA had recommended that we contact you directly to request a sample" of Thalomid for bioequivalence testing, and noted that "obtaining samples through other traditional channels is nearly impossible."

86. On October 20, 2005, Celgene responded, stating that it needed additional time to consider Mylan's request. Celgene claimed that this extra time was necessary in order to consider granting Mylan's request to obtain samples for the purpose of performing bioequivalence studies, in order to comply with its REMS program protocols and "to avoid fetal exposure."

87. On December 19, 2005, Celgene provided a "complete" response, stating that Celgene would need the FDA's approval in order to sell Thalomid samples to Mylan outside the confines of its REMS program. Specifically, Celgene wrote: "[W]e recommend that you contact the FDA's [Division of Special

Pathogen and Transplant Products] to discuss the importance of the [Thalomid REMS] program to them." Furthermore, Celgene stated that if the FDA subsequently "contacts us in writing and recommends that we violate our [Thalomid REMS] program by providing you with the quantity of THALOMID you request, we will further evaluate your request at that time."

88. Accordingly, on January 11, 2006, Mylan wrote to the FDA, asking for the FDA's assistance in obtaining the necessary Thalomid samples required to perform its bioequivalence testing. Mylan attached its proposed restricted distribution protocols for the samples demonstrating its ability to avoid fetal exposure to Thalomid. Mylan received a response from the FDA on February 12, 2007, in which the FDA requested an investigational new drug application (IND) so that the FDA could "ensure that all appropriate safeguards for a clinical investigation with thalidomide are in place," as a substitute for the Thalomid REMS program.

89. The FDA further wrote that REMS programs were not intended to prevent the sale of samples to generic drug manufacturers:

> It is the FDA's view that certain restrictions are needed to ensure safe use of the drug; however, it is not the agency's intention to permit the restrictions of the [Thalomid REMS] program to prevent manufacturers of generic drugs from obtaining Thalomid for use in the bioequivalence testing necessary to obtain approval of an abbreviated new drug application for a thalidomide product. The agency believes that such bioequivalence studies can be conducted safely under either an IND or in circumstances that provide alternative assurance of patient safety. To ensure that the intention

> of Congress in enacting the generic drug approval provisions in section 505(j) is not frustrated by the terms of the [Thalomid REMS] program, FDA has notified Celgene that the agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid (including 200 units for the purpose of conducting bioequivalence (including dissolution) testing and 300 units for a limited number of retained samples) when Celgene has received confirmation in writing from the sponsor, its agent, or FDA that the sponsor of the study either has an IND in effect for the study or has otherwise provided the agency with sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the subjects.

90. On May 1, 2007, Mylan provided the FDA with its proposed thalidomide bioequivalence testing safety protocols.

91. On September 11, 2007, the FDA notified Mylan that its proposed safety protocols had been reviewed by the Division of Bioequivalence. It noted that the proposed protocols were deemed "acceptable."

92. On November 16, 2007, Mylan informed Celgene that the FDA had approved Mylan's proposed safety protocols, alleviating Celgene's concerns regarding providing the Thalomid samples to Mylan.

93. Although the FDA's approval of Mylan's safety protocols should have, according to its pronouncements, alleviated Celgene's purported concerns regarding safety, Celgene continued to refuse to sell samples of Thalomid to Mylan. Despite Celgene's willingness to provide Thalomid samples to non-competitor entities, Celgene has not provided Mylan, or any other generic drug manufacturer that has made similar requests, with any Thalomid samples.

94. Over the next three years, Mylan made many further attempts to acquire samples of Thalomid from Celgene. However, Celgene continuously employed delay tactics, including sending numerous requests for overly burdensome, irrelevant, and duplicative information to Mylan.

95. Mylan also sought to purchase samples of Revlimid from Celgene in order to develop and market a generic lenalidomide product. However, beginning in 2009, after Mylan attempted to purchase lenalidomide samples, Celgene employed familiar delay tactics, refusing to provide samples, even when informed of FDA approval for the proposed bioequivalence testing and safety protocols. To date, Celgene has not provided Mylan with samples of Revlimid.

96. On April 3, 2014, Mylan filed suit against Celgene under federal and state antitrust laws for its anticompetitive tactics to maintain monopoly power in the market for Thalomid and Revlimid (D. New Jersey, Case No. 14-cv-2094). Specifically, Mylan alleges that Celgene's cited safety concerns were merely a pretext for its refusal to deal with Mylan.

97. Mylan alleges that Celgene uses a "playbook of obstructing its generic competitors by gaming the regulatory system."

98. In support of Mylan's claims, the FTC filed an amicus brief in that case. Like the FDA letters, the FTC's brief noted that conduct such as that engaged in by Celgene is expressly prohibited by the FDAAA, which provides that brand-

name drug manufacturers may not use their REMS programs to impede the development of generic drugs and generic competition.

99. On December 22, 2014, Celgene's motion to dismiss Mylan's complaint was denied. On February 9, 2015, Celgene filed a Petition for Permission to Appeal with the United States Court of Appeals for the Third Circuit.

iv. Celgene Refused to Sell Samples of Revlimid to Dr. Reddy's Laboratories Despite the FDA's Express Approval to Do So

100. Dr. Reddy's is a pharmaceutical manufacturer based in Hyderabad, Telengana, India.

101. In August 2008, Dr. Reddy's requested samples of Revlimid from Celgene so that it could perform the bioequivalence testing necessary to submit its ANDA for generic lenalidomide. Celgene ignored Dr. Reddy's request.

102. In January 2009, Dr. Reddy's again requested the Revlimid samples from Celgene. Celgene's response was curt: "Celgene has no obligation to supply Dr. Reddy's with Revlimid and declines to do so."

103. Thereafter, in June 2009, Dr. Reddy's filed a Citizen Petition with the FDA, alleging that Celgene was continuing its practice of refusing to provide samples to a generic drug manufacturer for the purpose of bioequivalence testing.

104. In the face of much authority to the contrary, including that of the FDA, Celgene again employed its pretextual justification for refusing to provide the

requested samples: namely, that providing the samples would violate Celgene's Revlimid REMS program.

105. Thus, Celgene has engaged in an intentional pattern of anticompetitive conduct in which it uses its REMS programs as pretext for withholding samples of Thalomid and Revlimid. This course of conduct has been applied to all generic manufacturers who have sought to obtain, by paying retail price, samples of these drugs. As alleged herein, it is clear that Celgene has no legitimate business purpose for withholding such samples.

B. Celgene Fraudulently Obtained Patents to Obstruct Generic Competition and Maintain its Monopoly Power Over the Relevant Markets

106. In addition to using its REMS programs to block generic competitors from accessing samples of Thalomid and Revlimid, Celgene has fraudulently obtained numerous patents related to its plan for safe distribution of these drugs in an attempt to further extend its monopoly power.

107. The fraudulently obtained patents claim methods of delivering a drug to a patient while preventing exposure of a fetus or other contraindicated individual to that drug. The patents generally claim the use of registries to register patients, prescribers and pharmacies when the patient is using a particular drug that should not be exposed to a fetus or other contraindicated individual; testing and regularly retesting the patient for risks associated with the

drug (including pregnancy testing to prevent exposure to a fetus); counseling patients about the risk of the drug; limiting the amount of drug dispensed; and/or prescribing and dispensing the drug only after determining the risk is acceptable.

108. Celgene's patents on the procedures for safe distribution include the 6,045,501 patent, the 6,315,720 patent, the 6,561,976 patent, the 6,561,977 patent and the 6,755,784 patent (the "Distribution Method Patents"), and the 8,315,886 patent. Specifically, these patents claim the following subject matter and were filed and obtained on the following dates:

Patent Number	Patent No. Abbreviation	Subject Matter	Filing Date	Date Patent Obtained
6,045,501	'501 patent	Methods for delivering a drug to a patient while preventing exposure of a foetus or other contraindicated individual the drug	8/28/1998	4/4/2000
6,315,720	'720 patent	Methods for delivering a drug to a patient while avoiding the occurrence of an adverse side effect known or suspected of being caused by the drug	10/23/2000	11/13/2001
6,561,976	'976 patent	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	9/26/2001	5/13/2003

6,561,977	'977 patent	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	9/27/2001	5/13/2003
6,755,784	'784 patent	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	3/7/2003	6/29/2004
8,315,886	'886 patent	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	12/13/2010	11/20/2012

109. Celgene obtained FDA approval for Thalomid in 1998. It obtained FDA approval for Revlimid in December 2005.

110. When Thalomid was approved by the FDA in 1998, the only patent that Celgene listed in the Orange Book in connection with it was the '501 patent. However, as Celgene obtained these other patents, it added them to the Orange Book in connection with Thalomid. Moreover, when Revlimid was approved by the FDA in December 2005, Celgene also listed these patents in the Orange Book in relation to Revlimid. The '886 patent was added to the Orange Book for both drugs when it was obtained in 2012.

111. As discussed above, Celgene's decision to list these patents in the Orange Book was intended to delay entry of generics into the market and had no

legitimate purpose. Specifically, Celgene listed these patents in the Orange Book with the intent and purpose of discouraging generic manufacturers from developing generic thalidomide or lenalidomide and from filing the corresponding ANDAs.

112. Patent applicants are subject to a duty of good faith, candor, and disclosure in the filing and prosecution of a patent application. These duties require that anyone involved in prosecuting the patent application disclose all information that is material to the patentability of the claims.

113. Withholding information known to be material to patentability with intent to deceive the United States Patent and Trademark Office ("USPTO") constitutes inequitable conduct and renders a patent unenforceable.

114. Pursuant to 35 U.S.C. § 102, the existence of prior art is material to patentability because it bears on the novelty of the invention.

115. Procedures for safe distribution and use of dangerous drugs like Thalomid and Revlimid is not a novel concept. In fact, these procedures have been discussed, written about, and utilized for years prior to Celgene's application for the aforementioned patents. Specifically, the procedures were discussed in the following:

a. The "Clozaril Patient Monitoring Service" ("CPMS") (a/k/a "Clozaril National Registry"), a program for the distribution of CLOZARIL™, which uses a national registry of

prescribers, patients and pharmacies;

b. Honigfeld, "Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis," *Psychiatric Services* 47(1): 52-56 (1996) ("*Honigfeld I*"), which describes the CPMS;

c. Honigfeld, *et al.*, "Reducing Clozapine-Related Morbidity and Mortality: 5 Years of Experience With the Clozaril National Registry," J. *Clin. Psychiatry* 59 (suppl 3): 3-7 (1998) ("Honigfeld II"), which also describes the CPMS;

d. The "Guide to the Clozaril Patient Monitoring Service," Novartis Pharmaceuticals UK Ltd. (Nov. 1997) ("the Guide"), which describes details of the CPMS;

e. The ACCUTANE® Pregnancy Prevention Program ("PPP") is a program for the distribution of Accutane, also known to be a human teratogen;

f. The Accutane PPP Package ("PPP Package"), a 1994 patient and prescriber information package for Accutane, distributed by Roche Pharmaceuticals, which describes details of the PPP;

g. A Centers for Disease Control ("CDC") public meeting entitled

"Preventing Birth Defects Due to Thalidomide Exposure" and transcript from March 26, 1997, at which the risks associated with thalidomide use and procedures for safe distribution and use were discussed;

h. Zeldis, *et al.*, "S.T.E.P.S™: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide," *Clinical Therapeutics* 21(2): 319-30 (1999) ("*Zeldis*"), which describes the "System for Thalidomide Education and Prescribing Safety" or "S.T.E.P.S." developed by Celgene;

i. The September 4 and 5, 1997 Center for Drug Evaluation and Research of the Food and Drug Administration public meeting ("CDER Meeting") at which Celgene employee Bruce Williams explained that Clozaril and Accutane procedures were a "starting point" in developing distribution procedures for thalidomide; and

j. The September 9 and 10, 1997 public workshop held by the National Institutes of Health, FDA, and CDC, entitled "Thalidomide: Potential Benefits and Risks, Open Public Scientific Workshop" (the "NIH Meeting"), at which Celgene employee Bruce Williams gave a presentation about

a Celgene proposal "for a distribution and education system" for thalidomide.

116. Each of the above constitutes prior art that was material to patentability of the aforementioned Distribution Method Patents, which Celgene was required to, but did not, disclose to the USPTO.

117. Although Celgene did disclose some of this prior art in its '886 patent application, as with the Distribution Method Patents, it failed to disclose the existence of the PPP Package or CDC Transcript.

118. Thus, the aforementioned Distribution Method Patents and the '886 patent were obtained from the USPTO through knowing and willful fraud and are therefore unenforceable.

119. Moreover, Celgene caused the Distribution Method Patents and the '886 patent to be listed in the Orange Book with knowledge that they were fraudulently obtained from the USPTO and are unenforceable.

120. Celgene intentionally withheld prior art material to patentability with intent to deceive the USPTO in order to extend its monopoly in the markets for Thalomid and Revlimid by excluding generic competitors.

i. <u>The CPMS.</u>

121. The CPMS is a program for the distribution of CLOZARIL™ (also known as clozapine.) Clozaril, which is indicated and used for the treatment of

schizophrenia, can cause an increased risk of agranulocytosis, a potentially fatal blood disorder.

122. Clozaril is distributed through the CPMS, which employs a national registry for prescribers, patients and pharmacies in order to identify and reduce the risk of agranulocytosis associated with the use of Clozaril.

123. The CPMS employs the following steps, among others: registering prescribers, pharmacies and patients in a computerized registry; including information in the registry about the patient, such as baseline white blood cell ("WBC") counts, to determine the potential risk of agranulocytosis to the patient; performing blood testing for WBC counts before providing Clozaril to the patient; performing weekly blood testing for WBC counts after therapy has started; prescribing and dispensing a limited supply of Clozaril only after the prescriber determines that the risk is acceptable and provides the pharmacy with a report containing the patient's WBC count and the prescriber's assessment that the patient is eligible to receive Clozaril; denying or discontinuing treatment with Clozaril if the prescriber determines that the risk of agranulocytosis is unacceptable based on the testing; and providing weekly refills of Clozaril only after the same criteria for the initial prescription have been met again each week.

124. The CPMS qualifies as prior art to the claims of the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(b) because it was

commercially used in the United States more than one year before the earliest priority date of the Distribution Method Patents and the '886 patent.

125. The CPMS was not disclosed to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

ii. Honigfeld I.

126. Details of the CPMS are described in *Honigfeld I* (Honigfeld, "Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis," Psychiatric Services 47(1): 52-56 (1996)).

127. *Honigfeld I* qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(b) because it was publicly available and accessible more than one year before the earliest priority date of the Distribution Method Patents and the '886 patent.

128. The applicants, their agents and/or their attorneys did not disclose *Honigfeld I* to the USPTO during pendency of the applications from which the Distribution Method Patents issued.

iii. Honigfeld II.

129. Details of the CPMS are described in *Honigfeld II* (Honigfeld, et al., "Reducing Clozapine-Related Morbidity and Mortality: 5 Years of Experience With the Clozaril National Registry," *J. Clin. Psychiatry* 59 (suppl 3): 3-7 (1998)).

130. *Honigfeld II* qualifies as prior art to the '501 and '976 patents under 35 U.S.C. § 102(a) because it was publicly available and accessible before the earliest priority date of the '501 and '976 patents. *Honigfeld II* qualifies as prior art to the '720, '977, '784 and '886 patents under 35 U.S.C. § 102(b) because it was publicly available and accessible more than one year before the earliest priority date of the '720, '977, '784 and '886 patents.

131. The applicants, their agents and/or their attorneys did not disclose *Honigfeld II* to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

iv. The Guide.

132. Details of the CPMS are described in the Guide ("Guide to the Clozaril Patient Monitoring Service," Novartis Pharmaceuticals UK Ltd. (Nov. 1997)).

133. The Guide qualifies as prior art to the '501 and '976 patents under 35 U.S.C. § 102(a) because it was publicly available and accessible before the earliest priority date of the '501 and '976 patents. The Guide qualifies as prior art to the '720, '977, '784 and '886 patents under 35 U.S.C. § 102(b) because it was publicly available and accessible more than one year before the earliest priority date of the '720, '977, '784 and '886 patents.

134. The applicants, their agents and/or their attorneys did not disclose

the Guide to the USPTO during pendency of the applications from which the Distribution Method Patents issued.

v. The PPP (Accutane Pregnancy Prevention Program).

135. The PPP is a program for the distribution of ACCUTANE®, known generically as isotretinoin. Accutane is used to treat certain kinds of acne. Accutane is known to be a human teratogen.

136. The PPP was developed and established to limit or prevent fetal exposure to isotretinoin. The PPP employed, among other things: an information package for physicians warning of the dangers of administering isotretinoin to pregnant women; a patient informed consent form containing warnings detailing the risks associated with Accutane and the requirements to receive Accutane; required pregnancy testing and birth control counseling before the patient started treatment with Accutane; and a patient survey on compliance.

137. The PPP qualifies as prior art to the claims of the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(b) because it was commercially used in the United States more than one year before the earliest priority date of the Distribution Method Patents and the '886 patent.

138. The applicants, their agents and/or their attorneys did not disclose the PPP to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

vi. The Accutane PPP Package.

139. Details of the PPP are described in the PPP Package (a 1994 patient and prescriber information package) distributed by Roche Pharmaceuticals.

140. The PPP Package qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(b) because it was publicly available and accessible more than one year before the earliest priority date of the Distribution Method Patents and the '886 patent.

141. The applicants, their agents and/or their attorneys did not disclose the PPP Package to the USPTO during the pendency of the applications from which the Distribution Method Patents and the '886 patent issued.

vii. The CDC Meeting And Transcript.

142. On March 26, 1997, the CDC held a public meeting to discuss thalidomide and the risks associated with its use, entitled "Preventing Birth Defects Due to Thalidomide Exposure" (the "CDC Meeting").

143. The CDC Meeting was attended by at least two Celgene employees, Dr. Jerome Zeldis, then the Vice President of Medical Affairs at Celgene, and Mr. Bruce A. Williams, one of the named inventors on the Distribution Method Patents and the '886 patent.

144. The transcript of the CDC Meeting ("CDC Transcript") records the discussions that took place at the meeting. The CDC Transcript shows that the PPP

and the CPMS were discussed, as was the use of the elements of those two systems in designing a similar program for thalidomide.

145. During the CDC Meeting, the attendees discussed use of the following elements, among others, as part of a thalidomide distribution program: registration of male and female patients, pharmacies and prescribers; counseling patients about the risks of thalidomide and the need for contraception; required pregnancy testing before thalidomide is prescribed; monthly testing thereafter before refilling the prescription; providing proof to the pharmacy before the drug can be dispensed that the patient is not pregnant; providing contraceptives with the drug; limiting the length of the prescription to a monthly supply; and requiring revisits to the prescriber before refilling the prescription.

146. The CDC Transcript was publicly available and accessible under the Freedom of Information Act more than one year before the earliest priority date of the Distribution Method Patents and the '886 patent. Accordingly, the CDC Transcript qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(b).

147. The applicants, their agents and/or their attorneys did not disclose the CDC Meeting or the CDC Transcript to the USPTO during pendency of the applications from which the Distribution Method Patents and the '886 patent

issued.

viii. Zeldis.

148. *Zeldis* (Zeldis, et al., "S.T.E.P.S™: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide," *Clinical Therapeutics* 21(2): 319-30 (1999)), qualifies as prior art to the '720, '977 and '784 patents under 35 U.S.C. § 102(b) because it was publicly available and accessible more than one year before the earliest priority date of the '720, '977, '784 and '886 patents.

149. *Zeldis* is co-authored by Celgene employees, including Zeldis and named inventor Williams.

150. *Zeldis* describes the "System for Thalidomide Education and Prescribing Safety" or "S.T.E.P.S." (now known as Thalomid REMS) developed by Celgene, in conjunction with the FDA, to monitor and control access to thalidomide. *Zeldis* states that S.T.E.P.S. "is based in part on experience gained with other drugs – specifically isotretinoin and clozapine – that offer important clinical benefits but carry the potential for serious harm."

151. *Zeldis* discusses the systems established and used for Accutane (the PPP) and Clozaril (the CPMS), and states:

> Celgene has incorporated elements of both these successful programs into the S.T.E.P.S.™ program for controlling the distribution of thalidomide. Educational materials for patients and physicians and label warnings similar to those used in the isotretinoin program are coupled with

> clinician and patient registration and testing similar to those used in the clozapine program.

152. *Zeldis* cites *Honigfeld I* and *Honigfeld II* in its discussion of Clozaril.

153. The applicants, their agents and/or their attorneys did not disclose *Zeldis* to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

ix. The CDER Meeting And Transcript.

154. The CDER Meeting (a Center for Drug Evaluation and Research of the Food and Drug Administration public meeting on September 4 and 5, 1997 on the safety and efficacy of thalidomide) was recorded in a publicly available transcript ("CDER Transcript").

155. At least seven Celgene employees, including named inventor Williams, attended the CDER Meeting. Williams made a presentation on preventing fetal exposure to thalidomide at the CDER Meeting.

156. During this presentation at the CDER Meeting, Williams stated:

> [w]e recognize that there may be some models in the marketplace today which could serve as at least a starting point in our thinking as we develop this program. Two of them came to mind that I would like to just speak very briefly to, to indicate why we feel that they are relevant models, but also where we feel they may not go far enough for this particular circumstance. The first is one that this committee, particularly, is very familiar with. And that is Roche's Accutane, used to treat severe acne, and known to be a human teratogen.

157. Williams went on to describe the Accutane system, the PPP, and its

perceived drawbacks. Specifically, Williams noted as drawbacks the lack of a mandatory registry and an inability to determine at the pharmacy whether the patient has participated in Roche's programs.

158. Williams stated that the purported drawbacks with the PPP caused Celgene to look at other programs, specifically, the CPMS. He stated:

> In looking at how Sandoz structured this [Clozaril] system, we began to see that by taking elements from the Roche program [Accutane], elements from the Clozaril program and other unique elements, we would create a system that really would be state of the art, represent a significant step, we believe, forward in the ability to make drugs like thalidomide available to patients who need it, while at the same time providing a very high margin for protection.

159. The CDER Transcript qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(a) because it was publicly available and accessible under the Freedom of Information Act before the earliest priority date of the Distribution Method Patents and the '886 patent. The CDER Transcript also qualifies as prior art to the '720, '977 and '784 patents under 35 U.S.C. § 102(b) because it was publicly available and accessible under the Freedom of Information Act more than one year before the earliest priority date of the '720, '977 and '784 patents.

160. The applicants, their agents and/or their attorneys did not disclose the CDER Meeting or Williams' presentation at the CDER Meeting to the USPTO during the pendency of the applications from which the Distribution

Method Patents issued.

x. The NIH Meeting And Transcript.

161. The NIH Meeting (a National Institutes of Health, FDA, and CDC public workshop entitled "Thalidomide: Potential Benefits and Risks, Open Public Scientific Workshop" September 9 and 10, 1997) was recorded in a publicly available transcript ("NIH Transcript").

162. On September 10, 1997, inventor Williams gave a presentation at the NIH Meeting about a Celgene proposal "for a distribution and education system" for thalidomide.

163. During his presentation at the NIH Meeting, Williams stated that:

> [W]hen we started in this endeavor we looked to see what else was in the marketplace that might serve as a model. We accepted that we were unlikely to find any single model that carried all of the elements that would likely be necessary for this drug, but we did find two that in part covered many of the elements that might be required. Accutane, we heard about yesterday. Comprehensive educational program, counseling, and good contraception, informed consent, a package with integrated product warnings, and a surveillance system, albeit voluntary. Many elements that clearly with either change or updating or enhancement would likely be relevant to what needed to be done for thalidomide. We also heard about the Novartis program for Clozaril, a drug used to treat schizophrenia and introduced in an era where existing antischizophrenia drugs were not particularly effective for many patients. In addition they carried their own baggage of side effects. However, in a small proportion of patients who take this drug, a granular cytosis [sic] can develop in a very short period of time.

164. The NIH Transcript qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(a) because it was publicly

available and accessible under the Freedom of Information Act before the earliest priority date of the Distribution Method Patents and the '886 patent. The NIH Transcript also qualifies as prior art to the '720, '977 and '784 patents under 35 U.S.C. § 102(b) because it was publicly available and accessible under the Freedom of Information Act more than one year before the earliest priority date of the '720, '977 and '784 patents.

165. The applicants, their agents and/or their attorneys did not disclose the NIH Meeting or Williams' presentation at the NIH Meeting to the USPTO during pendency of the applications from which the Distribution Method Patents issued.

C. <u>The Distribution Method Patents are Unenforceable</u>

166. Any or all of the CPMS, Honigfeld I, Honigfeld II, the Guide, the PPP, the PPP Package, Zeldis, the CDC Meeting and Transcript, the CDER Meeting and Transcript, the NIH Meeting and Transcript, as well as Williams' presentations at any of these meetings, is material to the patentability of the Distribution Method Patents because:

a. Individually and/or in combination with one another, this prior art establishes a prima facie case of unpatentability under 35 U.S.C. §§ 102 and/or 103;

b. Had this prior art been disclosed to the USPTO, it would not have allowed any or all of the claims of the Distribution Method Patents

to issue;

c. Individually and/or in combination with one another, this prior art refutes or is inconsistent with positions taken by the applicants in opposing arguments of unpatentability relied on by the USPTO or asserting arguments in favor of patentability; and

d. Individually and/or taken together the prior art constitutes information that a reasonable USPTO Examiner reviewing the patent applications would consider important and/or material in determining whether to allow the proposed claims to issue.

167. As discussed above, patent application is an ex parte process that requires candor. *See* 37 C.F.R. § 1.56. The applicants of the Distribution Method Patents, including Bruce Williams, Celgene's agents, attorneys and/or others substantively involved in the prosecution, thus owed a duty of candor to the USPTO during the pendency of the applications from which the Distribution Method Patents issued. That duty of candor required the applicants to disclose information material to the applications from which the Distribution Method Patents issued. The applicants violated this duty of candor.

168. Specifically, during pendency of the applications from which the Distribution Method Patents issued, the applicants, including Williams, Celgene's agents, attorneys and/or others substantively involved in the prosecution, were

aware of the CPMS, *Honigfeld I*, *Honigfeld II*, the Guide, the PPP, the PPP Package, the CDC Meeting, the CDC Transcript, *Zeldis*, the CDER Meeting (including Williams' presentation) and Transcript and/or the NIH Meeting (including Williams' presentation) and Transcript.

169. Moreover, during the pendency of the applications from which the Distribution Method Patents issued, the applicants, including Williams, as well as Celgene's agents, attorneys and/or others substantively involved in the prosecution of the patents knew that the CPMS, *Honigfeld I*, *Honigfeld II*, the Guide, the PPP, the PPP Package, the CDC Meeting, the CDC Transcript, *Zeldis*, the CDER Meeting (including Williams' presentation) and Transcript and/or the NIH Meeting (including Williams' presentation) and Transcript was material to those applications.

170. In an effort to deceive the Patent Examiner and the USPTO, the applicants of the Distribution Method Patents, including Williams, as well as Celgene's agents, attorneys and/or others substantively involved in the prosecution intentionally and improperly withheld the CPMS, *Honigfeld I*, *Honigfeld II*, the Guide, the PPP, the PPP Package, the CDC Meeting, the CDC Transcript, *Zeldis*, the CDER Meeting (including Williams' presentation) and Transcript and/or the NIH Meeting (including Williams' presentation) and Transcript.

171. Moreover, the applicants of the Distribution Method Patents, including Williams, as well as Celgene's agents, attorneys and/or others substantively involved in the prosecution, knowingly and willfully misrepresented and omitted prior art that was material to patentability. But for these misrepresentations and omissions, the Distribution Method Patents would not have issued.

172. Because the Distribution Method Patents were obtained from the USPTO through knowing and willful fraud, they are unenforceable.

173. Moreover, despite Celgene's knowledge that the Distribution Method Patents were fraudulently obtained and are therefore unenforceable, Celgene caused the Distribution Method Patents to be listed in the Orange Book. Celgene intentionally listed the fraudulently obtained Distribution Method Patents in the Orange Book in order to discourage generic manufacturers from developing generic thalidomide and lenalidomide products and to prevent filing of the necessary ANDAs.

174. This anticompetitive conduct has successfully delayed generic competition in the market for both thalidomide and lenalidomide products.

175. Moreover, as Celgene has knowledge that the Distribution Method Patents were fraudulently obtained and are therefore unenforceable, its meritless lawsuits brought to enforce these unenforceable patents constitute sham litigation,

serving only the anticompetitive purpose of delaying the development and marketing of generic thalidomide and lenalidomide products.

D. The '886 Patent Is Unenforceable

176. On December 13, 2010, after both Barr (discussed above) and Natco Pharma Limited ("Natco") had filed ANDAs for thalidomide, Celgene applied for yet another patent on its distribution procedures – the '886 patent.

177. While the '886 application did disclose much of the prior art not listed in connection with the Distribution Method Patents, Celgene's application for the '886 patent did not disclose the PPP Package or the CDC Transcript as prior art.

178. Had the USPTO been aware of those undisclosed prior art references, the USPTO would not have allowed any or all of the claims of the '886 patent to issue. Hence, both the PPP Package and CDC Transcript are material to the patentability of the '886 patent.

179. The PPP Package and the CDC Transcript are material to the patentability of the '886 patent because:

a. Individually and/or in combination with one another, they refute or are inconsistent with positions the applicants took in opposing arguments of unpatentability, which were relied on by the USPTO; and

b. Individually and/or taken together, they constitute information that a

reasonable Patent Examiner reviewing the application would consider important and/or material in determining whether to allow the proposed claims of the '886 patent to issue.

180. The USPTO issued the '886 patent on November 20, 2012.

181. Like the Distribution Method Patents, the '886 patent was obtained from the USPTO through knowing and willful fraud and is therefore unenforceable.

182. When Celgene obtained the '886 patent, it caused the patent to be listed in the Orange Book in connection with Thalomid and Revlimid with knowledge that it was fraudulently obtained from the USPTO and is unenforceable. Celgene listed the '886 patent in the Orange Book with the intent and purpose of discouraging generic manufacturers from developing generic thalidomide or lenalidomide products and preventing the submission of the necessary ANDA filings.

183. This anticompetitive conduct has successfully delayed generic competition in the market for both thalidomide and lenalidomide products.

184. The applicants of the '886 patent, their agents, attorneys and/or others substantively involved in the prosecution of the patent owed a duty of candor to the USPTO during the pendency of the applications from which the '886 patent issued. *See* 37 C.F.R. §1.56. As part of that duty of candor, they were

required to, but failed to, disclose information material to the application from which the '886 patent issued.

185. While the application from which the '886 patent issued was pending, the applicants, including Williams, as well as Celgene's agents, attorneys and/or others substantively involved in the prosecution, were aware of the PPP Package and the CDC Transcript.

186. While the application from which the '886 patent issued was pending, the applicants, including Williams, as well as Celgene's agents, attorneys and/or others substantively involved in the prosecution of the patent, knew that the PPP Package and CDC Transcript were prior art that was material to that application.

187. The applicants of the '886 patent, including Williams, as well as Celgene's agents, attorneys and/or others substantively involved in the prosecution, intentionally withheld the PPP Package and CDC Transcript in order to deceive the Patent Examiner.

188. But for these knowing and willful misrepresentations and omissions, the '886 patent would not have issued.

189. Celgene has engaged in sham litigation to enforce these fraudulently obtained patents, including commencing litigation against lenalidomide ANDA applicants Natco, Arrow International Limited ("Arrow"), and Watson

Laboratories, Inc. ("Watson") for a statutory violation of these unenforceable patents. Natco has alleged counterclaims of fraud on the patent office.

E. Celgene Filed Sham Litigation and Baseless Citizen Petitions against Barr, Natco, Arrow, and Watson to Prevent or Delay Generic Entry and Competition

190. In the extremely rare case where a generic manufacturer has been able to complete bioequivalence studies and submit an ANDA for a generic thalidomide or lenalidomide product, Celgene has responded by *inter alia* filing sham Paragraph IV Litigation or meritless Citizen Petitions with the anticompetitive goal of preventing or delaying generic entry and corresponding competition.

191. Specifically, in 2008, Celgene filed a sham lawsuit against Barr regarding its ANDA for thalidomide, alleging that Barr's proposed generic thalidomide product infringed Celgene's patents. In 2010, Celgene filed a sham lawsuit against Natco regarding Natco's ANDA for lenalidomide, claiming that Natco's proposed generic lenalidomide infringed on Celgene's patents.

192. The patents at issue in those cases, including among others the Distribution Method Patents, relate to Celgene's REMS programs and procedures for ensuring safe use of drugs, including Thalomid and Revlimid. As described by Barr and Natco in their answers and subsequent briefing, Celgene's patents related to REMS are invalid due to undisclosed prior art or for obviousness, under 35 U.S.C. §§ 102 and/or 103. As detailed above, Celgene knew its litigation to

enforce these patents would be unsuccessful because the patents are unenforceable; it brought the cases solely for the anticompetitive purpose of delaying market entry of generic thalidomide and lenalidomide products.

193. Celgene's sham lawsuit against Natco is still ongoing.

i. Celgene's Sham Litigation and Baseless Citizen Petition Against Barr

194. As discussed above, in September 2006, Barr filed an ANDA application with the FDA for a proposed generic thalidomide product. In connection with its ANDA, Barr filed a Paragraph IV Certifications, alleging that Celgene's patents were invalid.

195. After receiving notification of Barr's Paragraph IV Certifications, Celgene brought claims against Barr for patent infringement in this Court. Additionally, on September 20, 2007, Celgene filed a baseless Citizen Petition alleging safety concerns related the drug. Barr counterclaimed against Celgene, alleging monopolization, conspiracy to monopolize, and anticompetitive acts, including sham litigation.

196. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), Celgene's Paragraph IV Litigation against Barr triggered a 30-month stay of FDA approval for Barr's proposed generic thalidomide product.

197. On May 26, 2010, after most of the 30-month stay had expired, Barr

and Celgene announced that they had reached a confidential settlement. The settlement purportedly resolved both Celgene's patent litigation and Barr's antitrust counterclaims.

198. The confidential settlement's terms may have included a payment from Celgene to Barr, known as a "pay-for-delay" or "reverse payment" agreement. Pursuant to a pay-for-delay agreement, the patent holder settles its patent infringement action by making a payment to the potential generic competitor in return for which the potential generic competitor agrees to either delay or indefinitely postpone introduction of its generic product. These settlements are inherently anticompetitive because they prevent the type of competition that Hatch-Waxman sought to foster and unlawfully prolong the patent holder's monopoly over the relevant drug market. Thus, pay-for-delay settlements allow the brand-name manufacturer to maintain its stranglehold on the relevant drug market to the detriment of consumers and to competition.

199. If the settlement contained a reverse payment, it suggests that Celgene's underlying patent claims were meritless. As discussed further below, the patents at issue in Celgene's case against Barr were method-of-use patents pertaining to Thalomid and Revlimid, rather than patents on the underlying pharmaceutical process.

200. Moreover, the patents at issue in that case were invalid on the grounds

of obviousness because they were based on academic studies and conferences. Therefore, Celgene's patent litigation against Barr was not undertaken in good faith because Celgene knew its patents were unenforceable. Rather, the litigation was designed to collusively and illegally ensure that Celgene could maintain its monopoly power.

201. On information and belief, Celgene's settlement with Barr had the anticompetitive effect of delaying and indefinitely postponing the testing and introduction of a generic thalidomide product, resulting in continued monopoly power and profits for Celgene to the detriment of consumers.

202. Concurrently with the patent litigation, Celgene filed a baseless Citizen Petition with the FDA, urging it not to approve Barr's application due to Celgene's alleged safety concerns.

203. Celgene's petition requested that the FDA withhold approval of any generic thalidomide product and specifically referenced Barr's ANDA by name and number. Celgene requested, in the alternative, that the FDA: (1) require the application for generic thalidomide to be subject to the same conditions of approval applied to Thalomid under Subpart H of 21 C.F.R., Part 314; and (2) prohibit the restricted distribution program for the generic thalidomide product from authorizing prescriptions for multiple myeloma and from registering patients with multiple myeloma and oncologists on the basis that it would violate Celgene's

orphan drug exclusivity. However, by Celgene's own admission, any such exclusivity expired in 2013. Moreover, the petition was devoid of any clinically meaningful evidence supporting Celgene's assertions.

204. The FDA did not respond to Celgene's petition. Upon entering into the confidential settlement that ended the patent litigation, Teva Pharmaceutical Industries (who purchased Barr while the litigation was pending), suddenly decided that it no longer wanted to enter the Thalomid market.

205. Celgene's Citizen Petition was used as another weapon in its anticompetitive arsenal and was filed for the sole purpose of interfering with competition in the thalidomide market. Celgene never publicly addressed its safety concerns surrounding the development of generic thalidomide, but rather, kept these concerns shrouded in secrecy. Celgene's efforts to keep the Citizen Petition secret belies its purported concerns related to safety and reveals its true motive, which is to keep generic thalidomide out of the marketplace.

ii. Celgene's Sham Litigation against Natco, Arrow, and Watson

206. Before Natco filed its ANDA in 2010, Celgene had listed the Distribution Method Patents, the '886 patent, and several patents it had obtained related to the chemical composition of Revlimid (including patent numbers 5,635,517 (the "'517 patent"), 6,281,230 (the "'230 patent"), 6,555,554 (the "'554 patent"), 7,119,106 (the "'106 patent"), 7,465,800 (the "'800 patent"), and

8,288,415 (the "'415 patent")), in the Orange Book in connection with NDA No. 21-880 (the application for the Revlimid RLD).

207. On August 30, 2010, Celgene received notice of Natco's Paragraph IV Certifications, which contained detailed factual and legal analyses as to why the Distribution Method Patents, as well as the '517, '230, '554, '106, and '800 patents, among others, are invalid, unenforceable, and/or not infringed by Natco's proposed generic lenalidomide products.

208. On or around September 24, 2010, Natco filed ANDA No. 201-452 seeking approval to manufacture and market 5 mg, 10 mg, 15 mg and 25 mg lenalidomide capsules ("Natco's generic lenalidomide products").

209. According to the ANDA, Natco's proposed generic lenalidomide products are bioequivalent to the RLD.

210. On October 8, 2010, Celgene filed Paragraph IV Litigation against Natco alleging patent infringement.

211. In 2012, more than two years after Natco filed its ANDA application, Celgene caused additional patents to be listed in the Orange Book in connection with Revlimid. Specifically, the '415 patent was added on or about November 16, 2012, and the '886 patent was added on or about December 20, 2012.

212. In response thereto, on March 14, 2013, Natco notified Celgene of additional Paragraph IV Certifications, which contain detailed factual and legal

statements as to why the '415 and '886 patents are invalid, unenforceable, and/or not infringed by Natco's generic lenalidomide products.

213. Thereafter, on or about April 10, 2013, nearly three years after Natco filed its ANDA, Celgene caused the 8,404,717 (the "'717 patent") to be listed in the Orange Book in connection with Revlimid.

214. On April 30, 2013, the USPTO issued the 8,431,598 patent ("'598 patent") to Celgene. To date, the '598 patent has not been listed in the Orange Book in connection with Revlimid.

215. On May 6, 2013, Celgene filed its Fifth Amended Complaint against Natco, Arrow and Watson, alleging that Natco's ANDA products would infringe the Distribution Method Patents, the '886 patent, and the '517, '230, '554, '106, '800, '415, '717 and '598 patents, which the defendants denied.

216. The invalidity of the Distribution Method Patents is discussed in Sections V.B. and V.C.

217. As Natco has responded in the patent infringement case, the '517, '230, '554, '106, '800, '415, '717, and '589 patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or doctrines of double-patenting. Furthermore, Natco's generic lenalidomide products do not infringe Celgene's '800 patent, because Natco's generic lenalidomide products do not contain lenalidomide hemihydrate.

218. In the course of the litigation, Natco filed counterclaims against Celgene, alleging fraud on the U.S. Patent and Trademark Office, and invalid or unenforceable patents.

219. Like its litigation against Barr, Celgene's litigation against Natco has no legitimate business purpose and only serves to further Celgene's monopoly in the market for lenalidomide products.

F. Celgene's Confidential Settlements with Barr and Lannett Had Anticompetitive Repercussions

239. As described above (paragraphs 79, 197-199), Celgene reached confidential settlements with both Barr and Lannett. These settlements may have had additional anticompetitive repercussions.

240. On information and belief, there may have been anticompetitive terms for the settlement between Celgene and Lannett, such as a promise to delay submission of the ANDA, or delay putting the drug to market after obtaining approval.

241. On information and belief, Celgene may have agreed to sell Thalomid to Lannett under the terms of the settlement, because Lannett announced in late 2013 that its bioequivalence studies were going well. Lannett filed its ANDA in late 2014 and provided notice of its Paragraph IV Certifications to Celgene on December 22, 2014. Celgene sued Lannett, alleging patent

infringement, on January 13, 2015. That case is currently pending (D.N.J. 2015-cv-00697).

G. Celgene's Anticompetitive Scheme Delayed Generic Entry into the Relevant Markets and Harmed Competition

242. Celgene's anticompetitive scheme has successfully blocked and delayed generic competition from entering the markets for thalidomide and lenalidomide, has disrupted the normal distribution channels, has flaunted the applicable statutory and regulatory mechanisms, and has excluded potential generic competitors from the most efficient means of distributing their products, including those who have actually filed ANDAs for generic thalidomide and lenalidomide.

243. But for Celgene's anticompetitive conduct, generic Thalomid would have been brought to market long before the beginning of the class period. Moreover, as explained in detail above, but for Celgene's conduct, the generic market for thalidomide would likely contain numerous competitors, driving down the cost of thalidomide products to the benefit of consumers. Celgene's anticompetitive conduct included abuse of the Thalomid REMS program, fraud on the USPTO, sham litigation, including confidential settlements with anticompetitive effects, and baseless Citizen Petitions.

244. But for Celgene's anticompetitive conduct, generic Revlimid would

have been brought to market, at a minimum, within months of the beginning of the class period alleged here. Moreover, as explained in detail above, but for Celgene's conduct, the generic market for lenalidomide would likely contain at least one generic competitor – if not numerous competitors – driving down the cost of lenalidomide products to the benefit of consumers. Celgene's anticompetitive conduct included abuse of the Revlimid REMS program, fraud on the USPTO and sham litigation. As alleged herein, all of Celgene's patents on Revlimid are invalid under 35 U.S.C. §§ 101, 102, 103, 112, and/or doctrines of double-patenting, or would not be infringed by a competing generic. Thus, but for Celgene's sham lawsuit, Natco would have brought to market a generic version of Revlimid.

245. But for Celgene's anticompetitive refusals to sell samples of Thalomid and Revlimid to any generic competitor, there is an extremely high likelihood that generic versions of these drugs would have entered the market.

246. Celgene's unlawful refusal to deal with would-be generic competitors prevented those would-be competitors from conducting bioequivalence testing and from filing ANDAs for generic thalidomide and lenalidomide products. But for Celgene's unlawful conduct, the FDA would have given final approval to the pending generic capsule manufacturers and allowed them to enter the market.

247. Celgene has no legitimate justification for its scheme, most notably, because its actions directly harmed competition and therefore harmed consumers.

The enormous cost savings offered by generic drugs (and, correspondingly, the anticompetitive harm caused by suppressing generic competition to Thalomid and Revlimid) outweigh any cognizable, nonpretextual procompetitive justifications Celgene could potentially offer. Celgene's monopoly power, as alleged more fully below, was maintained through willful exclusionary conduct, as distinguished from growth or development as a consequence of a superior product, business acumen or historic accident. Neither Celgene's scheme as a whole, nor any of its constituent parts, constituted meritorious competition.

248. As a result of Celgene's anticompetitive conduct, Plaintiff and class members still do not have access to either generic thalidomide or lenalidomide products.

249. As alleged in more detail below, Celgene violated state statutes and common law through its anticompetitive scheme to improperly maintain and extend its monopoly power by blocking and delaying competition from lower-priced generic thalidomide and lenalidomide products.

VI. CLASS ALLEGATIONS

250. Plaintiff brings this action on its own behalf and, under Rules 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, as a representative of a Class defined as follows:

> All persons or entities who purchased, paid and/or provided reimbursement for some or all of the purchase price for thalidomide or lenalidomide in

any form, in the United States and its territories for consumption by themselves, their families, their constituents, members, employees, insureds, participants, or beneficiaries at any time during the period November 7, 2010 through and until the anticompetitive effects of Defendant's unlawful conduct cease (the "Class").

251. The following persons or entities are excluded from the proposed Class:

a. Defendant and their officers, directors, management, employees, subsidiaries, or affiliates;

b. All federal or state governmental entities, except for cities, towns, or municipalities with self-funded prescription drug plans;

c. All persons or entities who purchased Revlimid or Thalomid for purposes of resale or directly from Defendant or their affiliates;

d. Fully insured health plans (*i.e.*, Plans that purchased insurance from another third party payor covering 100% of the Plan's reimbursement obligations to its members);

e. Any "flat co-pay" consumers whose purchases of Revlimid or Thalomid were paid in part by a third party payor and whose co-payment was the same regardless of the retail purchase price;

f. Any Judges or Justices involved in this Action and any members of their immediate families.

252. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes the Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

253. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by Celgene, *i.e.*, they paid artificially inflated prices for Thalomid and

Revlimid and were deprived of the benefits of competition from less-expensive generic versions of these drugs as a result of Celgene's wrongful conduct.

254. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

255. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation.

256. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Celgene has acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Celgene's wrongful conduct.

257. Questions of law and fact common to the Class include:

a. whether Celgene unlawfully maintained monopoly power;

b. whether Celgene engaged in an anticompetitive scheme to suppress generic competition for Thalomid and/or Revlimid;

c. whether a reasonable petitioner would have expected the arguments made in Celgene's "Citizen Petition" against Barr to succeed;

d. whether Celgene's "Citizen Petition" was submitted to interfere with competition;

e. whether there exist cognizable, nonpretextual procompetitive justifications, which Celgene's challenged conduct was the least restrictive means of achieving, that offset the harm to competition in

the market(s) in which Thalomid and Revlimid is sold;

f. whether direct proof of Celgene's monopoly power is available, and if available, whether it is sufficient to prove Celgene's monopoly power without the need to also define a relevant market;

g. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

h. whether Celgene's scheme, in whole or in part, has substantially affected interstate commerce;

i. whether Celgene's scheme, in whole or in part, caused antitrust injury to Plaintiff and the members of the Class in the nature of overcharges; and

j. the quantum of overcharges paid by the Class in the aggregate.

258. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

259. Plaintiff knows of no difficulty to be encountered in this action that would preclude its maintenance as a class action.

VII. ADDITIONAL FACTUAL ALLEGATIONS

A. The Effects of Celgene's Anticompetitive Scheme on Competition and Damages to Plaintiff and the Class

260. Celgene's overarching anticompetitive scheme consisted of, *inter alia*: using its REMS programs as a pretext to deny generic manufacturers access to samples of Thalomid and Revlimid necessary to complete bioequivalence testing; fraudulently obtaining various patents, including the Distribution Method Patents; engaging in sham litigation and, in certain cases, entering into confidential settlements that may have included an anticompetitive reverse payment; and filing baseless Citizen Petitions with the FDA. Celgene's conduct was intended to, and did, suppress generic competition in the markets for thalidomide and lenalidomide, both as a whole and in its individual parts. Celgene has successfully delayed and prevented the sale of generic thalidomide and lenalidomide products by suppressing the ability of generic manufacturers to compete through the most efficient means of competition available under the applicable statutory and regulatory construct, including the Hatch-Waxman Act.

261. Celgene's anticompetitive scheme was motivated by its desire to maintain its monopoly power over the markets for thalidomide and lenalidomide capsules thus also maintaining its supracompetitive prices for, and profits from, these drugs. An overcharge at the highest level of distribution generally trickles down to each level below, ultimately resulting in higher prices paid by the end

payor for the product. This is especially true in the pharmaceutical market. Thus, but for Celgene's anticompetitive conduct which operated to stymie generic competition, Class Members would have had access to generic thalidomide and lenalidomide sooner and at lower, more competitive prices, and/or could have purchased brand-name Thalomid or Revlimid at competitive prices rather than supracompetitive prices.

262. During the relevant period, Plaintiff and other members of the Class purchased and/or provided reimbursement for all or part of the price of Thalomid and/or Revlimid. Thus, as a result of the anticompetitive conduct alleged herein, Plaintiff and all other class members were injured by paying inflated prices for Thalomid and Revlimid. But for Celgene's anticompetitive conduct, Plaintiff and all other class members would have paid less for Thalomid or Revlimid and/or would have had access to less expensive generic thalidomide and lenalidomide.

263. As a consequence, Plaintiff and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

B. The Effect of Celgene's Anticompetitive Scheme on Interstate and Intrastate Commerce

264. At all relevant times, Thalomid and Revlimid were manufactured and sold by Celgene and were shipped across state lines and sold to customers located outside their state of manufacture.

265. During the relevant time period, in connection with the purchase and sale of Thalomid and Revlimid, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

266. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. As alleged herein, Celgene's conduct occurred within the flow of, and has substantially affected, interstate commerce.

267. Celgene's anticompetitive conduct also has substantial effects on intrastate commerce, including because retailers within each state are prevented from offering less expensive generic thalidomide and lenalidomide to end-payors within each respective state.

C. Celgene's Monopoly Power

268. As alleged herein, at all relevant times, Celgene possessed and exercised monopoly power over the markets for Thalomid and Revlimid, because it had the power to raise and/or maintain the price of Thalomid and Revlimid at supracompetitive levels without losing substantial sales.

269. To the extent that Plaintiff is required to define the relevant market for purposes of proving that Celgene had monopoly power, Plaintiff alleges that

the relevant product markets are Thalomid in all its forms and dosage strengths and the respective AB-rated generic bioequivalents, and Revlimid in all its forms and dosage strengths and the respective AB-rated generic bioequivalents.

270. A small but significant, non-transitory increase in price by Celgene to Thalomid would not have caused a significant loss of sales to other drugs or products used for the same purposes, with the exception of AB-rated generic versions of Thalomid.

271. A small but significant, non-transitory increase in price by Celgene to Revlimid would not have caused a significant loss of sales to other drugs or products used for the same purposes, with the exception of AB-rated generic versions of Revlimid.

272. Thalomid does not exhibit significant, positive cross-elasticity of demand with respect to price, with any leprosy treatment or other product other than AB-rated generic versions of Thalomid.

273. Revlimid does not exhibit significant, positive cross-elasticity of demand with respect to price, with any multiple myeloma treatment or other product other than AB-rated generic versions of Revlimid.

274. Celgene needed to control only Thalomid and its AB-rated generic bioequivalents, and no other products, in order to maintain the price of Thalomid at supracompetitive levels and to reap monopoly profits. Only the

market entry of a competing, AB-rated generic version of Thalomid would render Celgene unable to maintain its supracompetitive prices for Thalomid without losing substantial sales.

275. Celgene needed to control only Revlimid and its AB-rated generic bioequivalents, and no other products, in order to maintain the price of Revlimid at supracompetitive prices and to reap monopoly profits. Only the market entry of a competing, AB-rated generic version of Revlimid would render Celgene unable to maintain its supracompetitive prices for Revlimid without losing substantial sales.

276. The relevant geographic market is the United States and its territories.

277. At all relevant times, the markets for Thalomid and Revlimid were characterized by high barriers to entry due to patent and other regulatory protections, and high costs of entry and expansion due to the nature of pharmaceutical drug development.

278. At all relevant times, Celgene controlled 100% of the relevant markets.

CLAIMS FOR RELIEF

COUNT I

MONOPOLIZATION AND MONOPOLISTIC SCHEME UNDER STATE LAW

279. Plaintiff incorporates by this reference the allegations in the above paragraphs as if fully set forth herein.

280. At all relevant times, Celgene possessed monopoly power in the relevant markets. Specifically, Celgene had the power to, and did, control prices in the relevant markets for Thalomid and Revlimid and deliberately interfered with generic manufacturers' attempts to enter the markets for Thalomid and Revlimid, preventing generic entry and prolonging its monopoly power.

281. As alleged above and incorporated herein, through its anticompetitive scheme, Celgene willfully maintained its monopoly power in the relevant markets through restrictive or exclusionary conduct, rather than by means of greater business acumen, superior product or historic accident, thereby injuring Plaintiff and the Class Members.

282. Celgene acted intentionally through its anticompetitive scheme to maintain its monopoly power over the relevant markets.

283. As alleged above and incorporated herein, Celgene's anticompetitive scheme harmed competition and injured Plaintiff and the Class Members.

284. To the extent Celgene is permitted to assert a justification for its conduct, there is and was no cognizable, nonpretextual, procompetitive justification for Celgene's anticompetitive conduct that outweighs such conduct's harmful effects. Even if such justification existed and Celgene were permitted to assert it, the scheme is and was broader than necessary to achieve such a purpose.

285. As a direct and proximate result of Celgene's illegal and monopolistic conduct, as alleged herein, Plaintiff and the Class were injured.

286. By engaging in the foregoing conduct, Celgene has intentionally and wrongfully maintained monopoly power in the relevant markets in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Thalomid and Revlimid in Arizona by members of the Class;

b. California Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to purchases of Thalomid and Revlimid in California by members of the Class.

c. D.C. Code §§ 28-4501, *et seq.*, with respect to purchases of Thalomid and Revlimid in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Thalomid and Revlimid in Florida by members of the Class.

e. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchases of Thalomid and Revlimid in Illinois by members of the Class.

f. Iowa Code §§ 553.1, *et seq.*, with respect to purchases of Thalomid and Revlimid in Iowa by members of the Class.

g. Kansas Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Thalomid and Revlimid in Kansas by members of the Class.

h. Me. Rev. Stat. Ann. 10 §§ 1101, *et seq.*, with respect to purchases of Thalomid and Revlimid in Maine by members of the Class.

i. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases of Thalomid and Revlimid in Michigan by members of the Class.

j. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases of Thalomid and Revlimid in Minnesota by members of the Class.

k. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of Thalomid and Revlimid in Mississippi by members of the Class.

l. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Thalomid and Revlimid in Nebraska by members of the Class.

m. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Thalomid and Revlimid in Nevada by members of the Class.

n. N.H. Rev. Stat. Ann. §§ 356.1, *et seq.*, with respect to purchases of Thalomid and Revlimid in New Hampshire by members of the Class.

o. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Thalomid and Revlimid in New Mexico by members of the Class.

p. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Thalomid and Revlimid in North Carolina by members of the Class.

q. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases of Thalomid and Revlimid in North Dakota by members of the Class.

r. Or. Rev. Stat. Ann. §§ 646.705, *et seq.*, with respect to purchases of Thalomid and Revlimid in Oregon by members of the Class.

s. 10 L.P.R.A. §§ 257, *et seq.*, with respect to purchases of Thalomid and Revlimid in Puerto Rico by members of the Class.

t. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchases of Thalomid and Revlimid in Rhode Island by members of the Class.

u. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases of Thalomid and Revlimid in South Dakota by members of the Class.

v. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Thalomid and Revlimid in Utah by members of the Class.

w. Vt. Stat. Ann. 9, §§ 2451, *et seq.*, with respect to purchases of Thalomid and Revlimid in Vermont by members of the Class.

x. W.Va. Code. §§ 47-18-1, *et seq.*, with respect to purchases of Thalomid and Revlimid in West Virginia by members of the Class.

y. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchases of Thalomid and Revlimid in Wisconsin by members of the Class.

COUNT II

ATTEMPTED MONOPOLIZATION UNDER STATE LAW

287. Plaintiff incorporates by this reference the allegations in the above paragraphs as if fully set forth herein.

288. At all relevant times, Celgene possessed monopoly power in the relevant markets. Specifically, Celgene had the power to, and did, control prices in the relevant markets for Thalomid and Revlimid and deliberately interfered with generic manufacturers' attempts to enter the markets for Thalomid and Revlimid, preventing generic entry and prolonging its monopoly power.

289. The natural, intended, and foreseeable consequence of Celgene's anticompetitive scheme was to control prices and exclude competition in the relevant markets.

290. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Celgene would succeed in achieving its goal of maintaining monopoly power in the relevant markets.

291. As a direct and proximate result of Celgene's illegal and monopolistic conduct, as alleged herein, Plaintiff and the Class were injured.

292. By engaging in the foregoing anticompetitive conduct, Celgene has intentionally and wrongfully attempted to monopolize the relevant markets in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases of Thalomid and Revlimid in Arizona by members of the Class;

b. California Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to purchases of Thalomid and Revlimid in California by members of the Class.

c. D.C. Code §§ 28-4501, *et seq.*, with respect to purchases of Thalomid and Revlimid in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Thalomid and Revlimid in Florida by members of the Class.

e. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchases of Thalomid and Revlimid in Illinois by members of the Class.

f. Iowa Code §§ 553.1, *et seq.*, with respect to purchases of Thalomid and Revlimid in Iowa by members of the Class.

g. Kansas Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Thalomid and Revlimid in Kansas by members of the Class.

h. Me. Rev. Stat. Ann. 10 §§ 1101, *et seq.*, with respect to purchases of Thalomid and Revlimid in Maine by members of the Class.

i. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases of Thalomid and Revlimid in Michigan by members of the Class.

j. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Thalomid and Revlimid in Minnesota by members of the Class.

k. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of Thalomid and Revlimid in Mississippi by members of the Class.

l. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Thalomid and Revlimid in Nebraska by members of the Class.

m. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Thalomid and Revlimid in Nevada by members of the Class.

n. N.H. Rev. Stat. Ann. §§ 356.1, *et seq.*, with respect to purchases of Thalomid and Revlimid in New Hampshire by members of the Class.

o. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Thalomid and Revlimid in New Mexico by members of the Class.

p. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Thalomid and Revlimid in North Carolina by members of the Class.

q. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases of Thalomid and Revlimid in North Dakota by members of the Class.

r. Or. Rev. Stat. Ann. §§ 646.705, *et seq.*, with respect to purchases of Thalomid and Revlimid in Oregon by members of the Class.

s. 10 L.P.R.A. §§ 257, *et seq.*, with respect to purchases of Thalomid and Revlimid in Puerto Rico by members of the Class.

t. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchases of Thalomid and Revlimid in Rhode Island by members of the Class.

u. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases of Thalomid and Revlimid in South Dakota by members of the Class.

v. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Thalomid and Revlimid in Utah by members of the Class.

w. Vt. Stat. Ann. 9, §§ 2451, *et seq.*, with respect to purchases of Thalomid and Revlimid in Vermont by members of the Class.

x. W.Va. Code. §§ 47-18-1, *et seq.*, with respect to purchases of Thalomid and Revlimid in West Virginia by members of the Class.

y. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchases of Thalomid and Revlimid in Wisconsin by members of the Class.

COUNT III

UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

293. Plaintiff incorporates by this reference the allegations in the above paragraphs as if fully set forth herein.

294. As a direct and proximate result of Celgene's anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and Class

members were deprived of the opportunity to purchase less expensive, generic versions of thalidomide and lenalidomide and were forced to pay higher prices for each drug.

295. Plaintiff and the Class members paid and continue to pay supracompetitive prices for brand-name Thalomid and Revlimid. The value they receive is much lower than the price they are required to pay because, absent Celgene's unlawful anticompetitive conduct, Plaintiff and the Class would be able to purchase bioequivalent generic drugs at substantially lower prices.

296. Celgene engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the following state consumer protection statutes:

a. Arizona Rev. Stat. §§ 44-1521, *et seq.*, with respect to purchases of Thalomid and Revlimid in Arizona by members of the Class;

b. Ark. Code §§ 4-88-101, *et seq.*, with respect to purchases of Thalomid and Revlimid in Arkansas by members of the Class.

c. California Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of Thalomid and Revlimid in California by members of the Class.

d. D.C. Code §§ 28-3901, *et seq.*, with respect to purchases of Thalomid and Revlimid in the District of Columbia by members of the Class.

e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Thalomid and Revlimid in Florida by members of the Class.

f. Idaho Code §§ 48-601, *et seq.*, with respect to purchases of Thalomid and Revlimid in Idaho by members of the Class.

g. Kansas Stat. Ann. §§ 50-623, *et seq.*, with respect to purchases of Thalomid and Revlimid in Kansas by members of the Class.

h. Mich. Comp. Laws Ann. §§ 445.901, *et seq.*, with respect to purchases of Thalomid and Revlimid in Michigan by members of the Class.

i. Minn. Stat. §§ 325F.68, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Thalomid and Revlimid in Minnesota by members of the Class.

j. Mo. Rev. Stat. §§ 407.010, *et seq.*, with respect to purchases of Thalomid and Revlimid in Missouri by members of the Class.

k. Neb. Code Ann. §§ 59-1601, *et seq.*, with respect to purchases of Thalomid and Revlimid in Nebraska by members of the Class.

l. Nev. Rev. Stat. Ann. §§ 598.0903, *et seq.*, with respect to purchases of Thalomid and Revlimid in Nevada by members of the Class.

m. N.H. Rev. Stat. Ann. §§ 358-A, *et seq.*, with respect to purchases of Thalomid and Revlimid in New Hampshire by members of the Class.

n. N.M. Stat. Ann. §§ 57-12-1, *et seq.*, with respect to purchases of Thalomid and Revlimid in New Mexico by members of the Class.

o. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases of Thalomid and Revlimid in New York by members of the Class.

p. N.C. Gen. Stat. §§ 75-1.1, *et seq.*, with respect to purchases of Thalomid and Revlimid in North Carolina by members of the Class.

q. Or. Rev. Stat. Ann. §§ 646.605, *et seq.*, with respect to purchases of Thalomid and Revlimid in Oregon by members of the Class.

r. 73 Pa. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases of Thalomid and Revlimid in Pennsylvania by members of the Class.

s. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases of Thalomid and Revlimid in Rhode Island by members of the Class.

t. S.D. Codified Laws §§ 37-24-1, *et seq.*, with respect to purchases of Thalomid and Revlimid in South Dakota by members of the Class.

u. Utah Code Ann. §§ 13-11-1, *et seq.*, with respect to purchases of Thalomid and Revlimid in Utah by members of the Class.

v. Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases of Thalomid and Revlimid in Virginia by members of the Class.

COUNT IV

INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR CELGENE'S VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT

297. Plaintiff incorporates by this reference the allegations in the above paragraphs as if fully set forth herein.

298. Plaintiff's allegations described herein and in claims I through III constitute violations of Section 2 of the Sherman Act, as well as violations of various state laws.

299. Plaintiff and the members of the Class seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable laws, to remedy the anticompetitive market effects caused by Celgene's unlawful conduct, and other relief so as to ensure that Celgene does not repeat similar anticompetitive conduct in the future.

COUNT V

UNJUST ENRICHMENT UNDER STATE LAW

300. Plaintiff incorporates by this reference the allegations in the above paragraphs as if fully set forth herein.

301. Defendant has unjustly benefited from reaping monopoly profits on its sales of Thalomid and Revlimid resulting from the unlawful and inequitable acts alleged throughout this Complaint.

302. Defendant obtained this financial benefit through its unlawful and inequitable acts traceable to overpayments for Thalomid and Revlimid by Plaintiff and members of the Class.

303. Plaintiff and the Class have conferred upon Defendant an economic benefit, in the nature of monopoly profits resulting from unlawful overcharges and supracompetitive prices, to the economic detriment of Plaintiff and the Class.

304. It would be futile for Plaintiff and the Class to seek a remedy from any party with whom they have privity of contract.

305. It would be futile for Plaintiff and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Thalomid or Revlimid, as they are not liable and would not compensate Plaintiff for Celgene's unlawful conduct.

306. The economic benefit of overcharges and monopoly profits derived by Defendant through charging supracompetitive and artificially inflated prices for Thalomid and Revlimid is a direct and proximate result of Defendant's unlawful practices.

307. The financial benefits derived by Defendant rightfully belong to Plaintiff and the Class, as Plaintiff and the class paid, as a result of Defendant's monopolistic conduct, supracompetitive prices during the Class period inuring to the benefit of Defendant.

308. It would be inequitable under unjust enrichment principles of the laws of all states and territories in the United States, except Ohio and Indiana, for Defendant to be permitted to retain any of the overcharges for Thalomid and Revlimid derived from Defendant's unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

309. Defendant is aware of and appreciates the benefits bestowed upon it by Plaintiff and the Class.

310. Defendant should be compelled to disgorge in a common fund for the benefit of Plaintiff and the Class all unlawful or inequitable proceeds it received.

311. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendant traceable to Plaintiff and the Class.

312. Plaintiff and the Class have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, respectfully prays that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be provided to the Class, and declare Plaintiff the representative of the class described herein;

B. Enter judgment against Defendant and in favor of Plaintiff and the Class;

C. Declare the acts alleged herein to be unlawful under the state statutes set forth above, and the common law of unjust enrichment of the states and territories set forth above;

D. Permanently enjoin Defendant pursuant to sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) & 26, from continuing its unlawful conduct, so as to ensure that the Defendant does not repeat such anticompetitive conduct in the future;

E. Grant Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendant's unjust enrichment and award Plaintiff damages as provided by law in an amount to be determined at trial;

F. Award the Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

G. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by Defendant's unlawful conduct, as the Court deems just.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38, Plaintiff, on behalf of itself and the Class, demands a trial by jury on all issues so triable.

Dated: March 3, 2015

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